Exhibit B

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October 13, 2022

VIA GUARANTEED SUBPOENA
Custodian of Records
Northwell Health, Inc.
2000 Marcus Avenue
New Hyde Park, NY, 11042-1069

Re: Brian Joseph Gref v. American International Industries, Inc., et al. - Docket No.: 1:20-cv-5589

Dear Sir/Madam:

This office represents defendants, Whittaker, Clark & Daniels, Inc. ("defendant"), in the above-referenced matter, a case now pending in the United States District Court, Southern District of New York.

Enclosed please find defendant's Subpoena for certain records related to Dr. Jacqueline Moline. Please be advised that pursuant to same, **the files are due in our office on October 28, 2022**.

Please be advised that no documents should be released or produced until the date specified on this subpoena. Moreover, if you are notified that a motion to quash the subpoena has been filed, you should not produce or release the subpoenaed evidence unless ordered to do so by the Court or the release is consented to by all parties to the action.

If you have any questions, please do not hesitate to contact us. Thank you for your cooperation in this matter.

Very truly yours,

/s/ Janelle N. Winters
Janelle N. Winters

enc.

Office of Legal Affairs
Received
OCT 14 2022
3:30 PM
Adrienne Grimaldi
served by Rick Lettau
NYF INC.

4884-3707-1161v.1

UNITED STATES DISTRICT COURT

for the

Southern District of New York

Brian Joseph Gref

Plaintiff

v.

American International Industries, et al.,

Defendant

Civil Action No. 1:20-cv-5589

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Custodian of Records of Northwell Health, Inc. 2000 Marcus Avenue, New Hyde Park, NY, 11042-1069

(Name of person to whom this subpoena is directed)

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material:

See "Attachment A"

Place:	Date and Time:
Landman, Corsi, Ballaine & Ford, P.C. 120 Broadway #1301, New York, NY 10271	10/28/2022 9:00 am

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: _____

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/ Janelle Winters

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Whittaker, Clark & Daniels, Inc., who issues or requests this subpoena, are: Landman, Corsi, Ballaine & Ford, P.C., Janelle N. Winters, One Gateway Center, 22nd Floor, Newark, NJ 07102 - (973) 632-2700

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 1:20-cv-5589

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of

$ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

ATTACHMENT A

1. Any and all records (whether typed, handwritten or computer generated) pertaining to or related to:

   a. Compensation paid to Dr. Jacqueline Moline ("Dr. Moline") by Northwell Health, Inc. ("Northwell") during the last five years, including billing records, invoices, W-9s, 1099, or any other applicable IRS documents.

   b. Revenue from Dr. Moline's work as an expert witness.

   c. Compensation agreements and contracts between Northwell and Dr. Moline and Dr. Moline and other persons or entities.

2. Dr. Moline's publications that she authored or co-authored while employed by Northwell.

3. All correspondence, emails, documents, and other means of transmittal of information relating to any publication authored or co-authored by Dr. Moline while employed by Northwell, including her article entitled, *"Mesothelioma Associated With the Use of Cosmetic Talc,"* attached **as Exhibit 1.**

4. With respect to **Exhibit 1**, copies of all Reports written by Dr. Moline on Northwell letterhead / stationary with respect to each of the 33 individuals included in the study.

5. With respect to **Exhibit 1**, all information, materials, and/or data relied upon by Dr. Moline including the underlying litigation materials relating the individuals included in the study, including "deposition transcripts," "other legal documents associated with the case," documents or notes relating to any "in-person interview" referred to in Dr. Moline's deposition by Dr. Moline and counsel, who retained her in cases MID-L-6651-16AS and MID-L-7336-16AS. (*See* excerpts of Dr. Moline's deposition testimony in those cases, attached as **Exhibit 2**).

6. All communications to or from Dr. Moline with any person or entity regarding the Ronald E. Gordon et al., publication entitled: *"Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women." See* **Exhibit 3**.

7. All communications by Dr. Moline relative to **Exhibit 3**, including correspondence or emails with its authors, Dr. Ronald Gordon, Sean Fitzgerald, and James Millette, in the last five years.

8. A business record Affidavit or Declaration authenticating any documents produced in response to this *Subpoena Duces Tecum*, substantially in the form of **Exhibit 4**.

9. Spreadsheet in possession of Northwell identifying the 33 subjects of **Exhibit 1**, which lists the subjects' first and last names, brand(s) of talc they used, law firm representation, occupation(s), and date of diagnosis and/or date of birth.

EXHIBIT "1"

ORIGINAL ARTICLE

Mesothelioma Associated With the Use of Cosmetic Talc

Jacqueline Moline, MD, MSc, Kristin Bevilacqua, MPH, Maya Alexandri, JD, and Ronald E. Gordon, PhD

Objective: To describe 33 cases of malignant mesothelioma among individuals with no known asbestos exposure other than cosmetic talcum powder. **Methods:** Cases were referred for medico-legal evaluation, and tissue digestions were performed in some cases. Tissue digestion for the six cases described was done according to standard methodology. **Results:** Asbestos of the type found in talcum powder was found in all six cases evaluated. Talcum powder usage was the only source of asbestos for all 33 cases. **Conclusions:** Exposure to asbestos-contaminated talcum powders can cause mesothelioma. Clinicians should elicit a history of talcum powder usage in all patients presenting with mesothelioma.

BACKGROUND

Asbestos in all forms is recognized by the International Agency for Research on Cancer (IARC) as a human carcinogen and all forms of asbestos are recognized as the primary risk factor for malignant mesothelioma.[1–9] By the mid-1950s, over 60 cases of asbestos-related lung cancer had been published in the literature. In 1955, Doll[10] published a seminal paper describing the increased risk of lung cancer among asbestos-exposed workers. In 1960, Wagner et al[2] published a study of 33 cases of malignant mesothelioma among individuals who were exposed to asbestos in and around the crocidolite mines in South Africa. By the mid-20th century, as asbestos use rose in the industrialized world, diseases associated with its use also began their upward curve.[3,8,11,12] On average between 2003 and 2008 1.05 cases per 100,000 of malignant mesothelioma (MM) were diagnosed in the United States and in 2015, 2597 deaths resulted from the disease.[13,14]

The presence of asbestos in talc and talcum powder consumer products including body powder, baby powder, facial cosmetics, and pharmaceutical talc was first discussed in the medical and scientific literature beginning in the 1940s.[15–17] Asbestos contamination of talc products is understood to occur during the mining process, in which talc deposits overlap or lie in close proximity to naturally occurring asbestos deposits.[18–22] The natural presence of asbestos within talc deposits makes selective mining or the extrication of asbestos from mined talc nearly impossible.[19] During application in its commercial talcum powder form, asbestos fibers become airborne and can be inhaled.[23,24] In 1968, Cralley et al[25] found the presence of three different types of asbestos fibers in 22 of 22 talcum products tested (tremolite, anthophyllite, and chysotile). However, talcum powder is still widely produced and consumed with a reported 58.3 million adults using body and baby powder in the United States in 2017.[26]

While the relationship between occupational exposure to asbestos and mesothelioma is well established, multiple studies have shown that not all individuals who develop mesothelioma can pinpoint exposures to asbestos.[8,11] Among women, occupational exposure explains less than half of malignant mesothelioma cases.[27,28] Some studies have focused on conventional exposure categories that for women only reflect take home exposures from (male) family members who worked in one of the selected occupations. In one such study, data on home or personal use exposures were not collected, yet increased amounts of tremolite asbestos fibers noted in the lungs of women with MM with no identified source of asbestos contact led study authors to hypothesize that the tremolite could be related to talcum powder use.[28] The high prevalence of unexplained or, "idiopathic mesothelioma" among women necessitates further inquiry into potential non-occupational exposures, such as exposure to asbestos-contaminated talcum powder.

In light of these gaps in the existing literature, we present 33 cases of individuals with malignant mesothelioma who were exposed to commercial talcum powder products. Of those cases, we present six in detail, where the individuals had no other known exposure to asbestos and for whom tissue studies show the presence of asbestos commonly found in talcum powder (such as tremolite, and/or anthophyllite). For all 33 cases, other potential exposures to asbestos were considered, with no identified source apart from the talcum powder. The cases were referred to author J.M. for medico-legal evaluation as part of tort litigation, and tissue digestions were performed by author R.G. as part of this litigation. In every case, a pathology report confirmed the diagnosis of malignant mesothelioma. This study was conducted with approval from the Northwell Health Feinstein Institute for Medical Research (#18-0225 FIMR).

MATERIALS AND METHODS

Case Histories

Data gathered for all 33 patients were gathered from each individual's medical records and sworn testimony (deposition transcripts) of individuals. All cases were reviewed by an occupational physician with experience evaluating asbestos exposure in thousands of patients. Data abstracted included medical diagnosis, review of pathology reports confirming the diagnosis of malignant mesothelioma, and clinical course. Exposure data was obtained from sworn testimony by the cases, which included extensive questioning regarding all sources of asbestos exposure. This included family occupational histories (parents and anyone cohabitating with the patient) for all cases to assess potential asbestos exposure, hobbies that included use of products that might contain asbestos (such as ceramics), residence in an area that might have had asbestos industry leading to possible environmental exposures, known abatement of asbestos while the patient was in school, home renovations that might have used asbestos containing materials, and any other potential sources of asbestos exposure. Additional data related to family history of cancers was obtained from the sworn testimony. Any data related to potential genetic mutations such as BRCA1 associated protein-1 was collected, if present.

From the Northwell Health Department of Occupational Medicine Epidemiology and Prevention (Dr Moline, Ms Bevilacqua); Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead (Ms Alexandri); Department of Pathology, The Icahn School of Medicine at Mount Sinai (Dr Gordon), New York, New York.

Funding: No funds or external assistance were obtained by any outside source in the development, writing, analysis, or conclusions of this manuscript.

Conflicts of Interest: Authors J.M. and R.G. have served as expert witnesses in asbestos litigation, including talc litigation for plaintiffs.

Supplemental digital contents are available for this article. Direct URL citation appears in the printed text and is provided in the HTML and PDF versions of this article on the journal's Web site (www.joem.org).

Clinical Significance: This manuscript is the first to describe mesothelioma among talcum powder consumers. Our case study suggest that cosmetic talcum powder use may help explain the high prevalence of idiopathic mesothelioma cases, particularly among women, and stresses the need for improved exposure history elicitation among physicians.

Address correspondence to: Jacqueline Moline, MD, Northwell Health, Great Neck, NY (jmoline@northwell.edu).

DOI: 10.1097/JOM.0000000000001723

Talcum powder exposure histories were reviewed based on sworn testimony by patients and in some cases, family members with first-hand knowledge of the use of talcum powder, such as parents who recalled using talcum powder while diapering the patient. Data including type of talcum powder used (Appendix 3, http://links.lww.com/JOM/A651), age at first use of talcum powder, and duration of use was obtained to ensure adequate latency from first exposure was present.[29] In some cases, individuals were also interviewed in person, and these data were merged with the data obtained in medical records and deposition transcripts.

The six cases described below also had tissue digestions performed by author R.G. These case reports are presented in greater detail; their clinical course was similar to all 33 cases evaluated, and the same rigor with respect to obtaining information related to any asbestos exposure was applied to all 33 cases.

Case 1

Case 1 is a 70-year-old woman who presented to a physician with shortness of breath and chest pain in January 2015. A chest x-ray revealed a small pleural effusion with left basilar atelectasis. In August 2015, a CT angiogram showed development of two subpleural nodules anterior to the lingula and a pleural based mass; a pleural effusion was still present. A thoracentesis was done and the cytology showed large clusters of cells suspicious for mesothelioma. A positron emission tomography (PET) scan showed pleural thickening and focal intense uptake inferiorly and posteriorly on the left side of her chest. In September 2015, she underwent thoracoscopic surgery. The pathology showed epithelial malignant mesothelioma with invasion of the visceral pleura and pulmonary parenchyma with tumor present at the stapled margin.

Case 1 applied loose face powder on a daily basis from the 1940s to the 1970s. Her mother also used the same loose face powder and Case 1 cleaned residual powder from her mother's dresser and clothing every other week from 1994 to 2012.

Electron microscopic analysis (EMA) of the lung tissue revealed anthophyllite fibers in a calculated concentrations of 3286 fibers per gram weight. There was also significant amount of fibrous and platy talc and aluminum silicates.

Case 1 was treated with four cycles of combination chemotherapy with cisplatin and pemetrexed for four cycles.

Case 2

In August 2015, Case 2, a 65-year-old woman presented with exertional dyspnea and dry cough. A chest x-ray showed a large left pleural effusion. A chest CT scan in September 2015 showed a freely-movable, large-volume, left pleural effusion, nodularity/lobulation of the left pleura, left lower lobe atelectasis, three nodules in the left upper lobe, and no hilar or mediastinal lymphadenopathy. A thoracentesis showed carcinoma cells. A PET-CT scan on September 22, 2016 reported showed abnormal deposits of tumor in the left pleura. There was no reported disease outside the chest.

Case 2 underwent a bronchoscopy in October, 2015. Pathology showed malignant mesothelioma, biphasic mixed type (50% sarcomatoid, 50% epithelioid). A second opinion confirmed the diagnosis. She underwent two cycles of chemotherapy with doxorubricin, ifosfide, and mensa and completed treatment in November. A PET scan showed no response to the chemotherapy. In December, Case 2 underwent left radical pleurectomy/decortication, resection of left hemidiaphragm, and one lymph node dissection. Surgical pathology showed residual biphasic malignant mesothelioma with negative nodes and negative margins. In January 2016, radiation oncology recommended adjuvant radiation therapy to the left chest, which she received in February and March of 2016. As of April 2016, Case 2 had no evidence of disease recurrence.

Case 2 reported starting to use talc around age eight or nine and would apply powder after her daily shower or bath. She would also use talcum powder when visiting her grandmother because she enjoyed the scent and would apply the powder before going on a date. She continued to use powder after getting married and used baby powder with all three of her children. In the early 2000s she began to regularly apply a fragrance and its matching talcum powder in the morning and at night, describing it as her signature scent. She also sprinkled the powder in her lingerie drawer and traveled with the powder which she would rub on her suitcases and other surfaces.

EMA of the lung tissue revealed anthophyllite fibers in a calculated concentration of 8625 fibers per gram wet weight with a limit of detection of 2875 fibers per gram wet weight. A significant amount of fibrous and platy talc was seen. EMA of the lymph node tissue revealed anthophyllite and tremolite fibers in a calculated concentrations of 34,500 fibers per gram wet weight with a limit of detection of 11,500 fibers per gram wet weight. They were seen in a ratio of 2:1 anthophyllite:tremolite/actinolite. All fibers counted were 5 μm or greater in length with aspect ratios greater than 8. There was also some amount of fibrous and platy talc noted in the lymph node tissue.

Case 3

In September 2014, Case 3, an 84-year-old woman, developed shortness of breath, a cough, and chest tightness. A chest x-ray in November 2014 showed a large left pleural effusion. A CT angiogram showed a large left pleural effusion with compressive atelectasis of the left middle and lower lobes and ground glass opacities in the left upper lobe and right lung. A thoracentesis showed carcinoma cells. Case 3 underwent a video thoracoscopy with pleural biopsy and evacuation of a pleural effusion. Pathology revealed a malignant epithelial neoplasm consistent with malignant epithelial mesothelioma. Case 3 then underwent a left pleurectomy and decortication in June 2015. The mesothelioma had spread to the lymph nodes and chest wall, and the pathology now showed malignant biphasic mesothelioma. Case 3 entered hospice care in September 2015 and died in late October 2015.

Case 3 worked as an elementary school teacher with no known occupational exposure to asbestos. Case 3 used talcum powder "before [she] was 12 and 13 years old," applying it under her arms and in her shoes daily. She shook the powder out of the can and applied it onto her body. She noted that her mother also used talcum body powder, and they shared a small bathroom. She used talcum powder beginning in the 1940s and continuing for decades, until her preferred brand was no longer available for purchase.

EMA of the lung tissue did not reveal any asbestos fibers above the limit of detection of 6900. However, there were a number of very small chrysotile asbestos fibers. Analysis of the lymph node tissue revealed tremolite asbestos fibers in calculated concentrations of 9409 fibers per gram wet weight with a limit of detection of 9409. All fibers counted were 5 μm or greater in length with aspect ratios greater than 20. There was also a significant amount of aluminum silicates, silica particles, and both fibrous and platy talc. Light microscopic analysis revealed a calculated concentration of 409 asbestos bodies per gram wet weight of lymph node tissue by phase contrast light microscopy.

Case 4

In August 2014, Case 4, a 66-year-old woman, developed abdominal pain and had a CT scan of the abdomen and pelvis that showed omental caking, ascites, a fluid pocket in the right lower quadrant, and enlarged diaphragmatic lymph nodes. She underwent a paracentesis and an omental biopsy in August 2014. The cytology revealed atypical mesothelial cells. She then underwent a laparotomy, appendectomy, omentectomy, and left salpingo-oophorectomy. The pathology showed malignant epithelioid mesothelioma. In September 2014, a PET/CT showed increased uptake in the abdomen consistent with malignant ascites, omental metastatic disease, and cardiophrenic

nodules. A thoracoscopy showed tumor covering the right hemidiaphragm. She was treated with multiple rounds of chemotherapy with cisplatin and pemetrexed and therapeutic paracenteses due to persistent ascites. Her tumor progressed, and she died in February 2016. She was 68 years old.

Case 4 grew up in a home where her mother used talcum powder "for as long as [she could] remember." She recalled personally using talcum powder starting around the age of 9 or 10, applying the powder to her armpits, groin, and around her body, using a powder puff. She applied talcum powder to her body for approximately 40 years. Case 4 had additional exposure to talcum powder in the 1960s while working as a licensed cosmetologist, applying talcum powder on clients' necks after a haircut. She shook the talcum powder onto the client's neck, and would wipe off the excess with a brush or blow dryer. She also used talcum powder inside the gloves that she donned prior to applying hair color.

EMA of the peritoneal tissue revealed chrysotile type asbestos fibers in a calculated concentration of 920 fibers per gram wet weight with a limit of detection of 920 fibers per gram wet weight. Fibrous and platy talc was also observed. Also seen were non-asbestiform tremolite and silica crystals.

Case 5

Case 5 was a 76-year-old woman who developed chest pain and fatigue in September 2015 and was diagnosed with viral pericarditis. A CT scan in October 2015 showed mild pericardial thickening and mild perihepatic ascites. She was treated with steroids for viral pericarditis. In late fall 2015, Case 5 developed decreased appetite, weight loss, tenderness around the umbilicus, and abdominal pain. In December 2015 she had an abdominal ultrasound that showed a mild to moderate amount of ascites. An abdominal CT scan showed slightly bilateral pleural thickening with minimal linear atelectatic change. There was copious perihepatic ascites extending to the right and left paracolic gutter and deep pelvis, nodularity at the paracolic gutter, and a right sided deep pelvic mass. A paracentesis was done and showed atypical epithelioid cells and tissue fragments with an inflammatory background. A laparoscopy showed peritoneal carcinomatosis with a diffuse miliary excrescence, a moderate sized pelvic mass and ascites. In January 2016 she underwent an exploratory laparotomy and resection of the omentum, spleen, resection of abdominal tumor, and resection of the abdominal wall tumor. The pathology showed malignant mesothelioma involving the omentum, spleen, colon, and mesentery, as well as the fibroadipose tissue of the peritoneum. Malignant mesothelioma also involved the parietal peritoneum as well as the appendix, with fibrous obliteration of the appendiceal lumen. Case 5 died in October 2017.

Case 5 had daily personal use of talcum body powder from the 1950s to the mid-1970s. She would pour the powder onto her hands and pat it under her arms, in her genital area, between her toes, and on her legs. When she was menstruating she would apply talcum powder on her feminine napkins and her underwear. She also applied talcum powder to her shoes. Case 5's husband also used talcum powder. Both Case 5 and her husband applied the powder in the bathroom. She shook the bathroom floor mat and cleaned up residual powder from the bathroom sink.

EMA of the omental tissue did not reveal any asbestos fibers above the limit of detection of detection of 651 fibers per gram wet weight. EMA of the lymph node tissue revealed chrysotile and anthophyllite asbestos fibers in a calculated concentrations of 20,700 fibers per gram wet weight with a limit of detection of 10,350 fibers per gram wet weight. All fibers counted were 5 μm or greater in length with aspect ratios greater than 20. There was also a significant amount of fibrous and platy talc as well as fibrous and platy aluminum silicates.

Case 6

Case 6 is a 44-year-old man who developed chest pain after playing hockey in 2012 and was evaluated in the Emergency Department. A CT scan that showed no pulmonary abnormalities. Case 6 continued to have chest pain over the next 4 years and underwent multiple cardiac evaluations. A CT scan in February 2016 showed increased pleural thickening or non-calcified pleural plaque along the right major fissure and anterior right hemithorax along the right upper lobe. A PET/CT scan in March 2016 showed unilateral hypermetabolic pleural fissural and non-fissural soft tissue abnormalities suspicious for malignancies involving the pleura. There were non-specific tiny parenchymal lung nodules. Case 6 underwent a tissue biopsy in March 2016. The pathology showed malignant epithelioid mesothelioma with invasion to the skeletal muscle.

Case 6 underwent neo-adjuvant chemotherapy with pemetrexed, cisplatin, and bevacizumab in April 2016. In May 2016, Case 6 underwent a mediastinoscopy which showed metastatic spread to the level VII lymph node. Additional chemotherapy was administered, which was not well tolerated. In July 2016, a parietal pleurectomy was done along the fissure between the upper and lower lobe. There was spread to the site of previous inferior right chest tube site. Case 6 developed acute thrombus in the right upper extremity. In September 2016, a chest x-ray showed unchanged right pleural thickening versus a small right pleural effusion. Three additional cycles of chemotherapy were recommended. A PET/CT scan in November 2017 showed a persistent hypermetabolic focus in the right anterobasal pleura and a slight increase in a right pleural effusion.

Case 6 was exposed to talcum powder beginning when he was an infant. His mother applied it to him after his bath until he was able to apply it himself, starting around the age of six. Case 6 recalled using the powder in the bathroom and in his room, and that there would be powder on his floor. He applied the talcum powder directly to his torso, groin, legs, and back, often twice a day after showering. He played hockey as a youth and used powder in his hockey gear before donning the equipment. He recalled getting mouthfuls of powder during the application. He often applied talcum powder once or twice a day after showering. He had no occupational exposure to asbestos.

EMA of the lymph node tissue revealed anthophyllite and tremolite asbestos fibers in a calculated concentrations of 17,250 fibers per gram wet weight with a limit of detection of 3450 fibers per gram wet weight. They were seen in a ratio of 2:3 anthophyllite:tremolite. All fibers counted were 5 μm or greater in length with aspect ratios greater than 14.7 or greater. There was also some amount of fibrous and platy talc along with platy aluminum silicates and magnesium aluminum silicates.

Tissue Sample Analysis

Tissue samples from six patients were analyzed: (a) lung and lymph node tissue from four of the patients diagnosed with pleural mesothelioma; and (b) lung and lymph node from two of the patients diagnosed with peritoneal mesothelioma. The tissue samples had been preserved in paraffin blocks or as formalin fixed tissues.

Tissue Digestion Protocols

Paraffin Blocks

The tissue was extracted from paraffin blocks was done according to the methodology described in Heller et al[30] and Wu et al.[31] The tissues were cut from the paraffin blocks and deparaffinized by melting and xylene treatment. They were brought to water, blotted and weighted. The tissues were digested with KOH and the inorganic pellet cleaned with distilled water by multiple centrifugation steps on an asbestos locator grid coated with formvar. In

addition, 250 μL samples were prepared using a cytocentrifuge onto a standard glass slide to identify ferruginous bodies and longer fibers by phase contrast microscopy.

Formalin Fixed Tissue

This protocol is similar to above without the deparaffinizing step as described in [23,39]. Controls for both the paraffin and formalin fixed tissues included looking at the paraffin, if from blocks, the formalin, if from fixed wet tissue, or any other materials used to process the tissue to view the remaining inorganic material on the grids.

Asbestos Fiber Counting

The grids were analyzed two ways: (a) transmission electron microscopy (TEM) using a standard fiber-counting protocol (23,40)[23,32] on 800 grid openings; and (b) phase contrast light microscopy on two cytocentrifuge preparations per tissue type in accordance with a standard asbestos body-counting protocol (23,40).[23,32] Asbestos fibers were evaluated to determine whether they met the definition of a fiber, which includes having at a 5:1 length:width ratio and parallel sides and at least 5 μm in length. The fibers were also analyzed by Energy Dispersive Spectroscopy (EDS) to determine the ratio of elements contained in the fibers and by Selected Area Electron Diffraction (SAED) to confirm the crystalline structure of the fiber to confirm that they were asbestos. To evaluate for potential contamination, control samples were prepared from the same distilled water used to wash the samples and the paraffin surrounding the tissue. Verification techniques of fiber counting were used for quality control and quality assurance. All fibers, regardless of size, were counted in 800 grid openings.

Calculating Asbestos Fiber Concentration

TEM and PCM

Asbestos fiber concentration in the samples examined with transmission electron microscopy was calculated (see Appendix 1, http://links.lww.com/JOM/A649). The 250 μL samples centrifuged onto standard microscope slides were examined using phase contrast light microscopy (Appendix 2, http://links.lww.com/JOM/A650). The asbestos fiber concentration in these samples was calculated (see Appendix 2, http://links.lww.com/JOM/A650).

Control Samples

Background control samples were obtained at autopsy or from surgical specimens from pulmonary or obstetrical and gynecologic pathologists. Samples included lung, thoracic, mesenteric and abdominal lymph nodes, abdominal tissue, ovaries, fallopian tubes, uteri and mesentery tissue. Exposure histories had been obtained by treating pulmonologists or surgeons from all individuals; all were screened for asbestos exposure from personal use, family exposure, and personal or family use of talcum powder. For those patients in whom there was any question of asbestos exposure from any source, the pathologists conferred with the treating clinician to ensure there was no known asbestos exposure. If there was potential asbestos exposure, the specimens were not included in the group. As a result, the background control specimens reflect only asbestos exposure from the overall community.

RESULTS

The data associated with the exposure history of all 33 patients is presented in Table 1. The table identifies talcum powder as the only asbestos exposure these patients have experienced. No individual identified any asbestos exposure apart from contaminated talcum powder from workplace or household exposures.

Table 2 provides the results of the fiber burden analyses for the six cases in which asbestos fibers were identified in the anatomic vicinity of the patients' mesotheliomas. Uniformly, the tissue fiber burdens reveal the presence of the following: talc, aluminum silicates, aluminum magnesium silicates, silica crystals, and asbestos fibers. The asbestos fibers are all anthophyllite, tremolite, and/or chrysotile. These three types are typical contaminants of talcum powders.[19] They have been identified as contaminants in talcum powders in repeated laboratory testing at numerous institutions.[33–37] The tissue fiber burdens contained no amosite or crocidolite, commercial amphibole asbestos fibers. Testing results of talcum powders have failed to show the presence of commercial amphiboles.

Table 3 presents the asbestos fiber burden results from background controls in tissues from autopsy and surgical population with no evidence of ovarian cancer or other malignancy, and with no known asbestos exposure. The lung and lymph nodes sampled showed only chrysotile and non-commercial amphibole asbestos in a small percentage of control samples—six of the 35 control samples, or 17%. All women with asbestos present were over 60 years of age. While asbestos is present at extremely low concentrations in the ambient air,[38] in the control samples presented in the study, there was no evidence of asbestos in women under the age of 60 years of age. Two fibers were seen in two specimens and one fiber was seen in four samples, all under 1 μm in size. The asbestos fiber burdens in the six talc exposed patients were all greater than the control population. No aluminum silicates, aluminum magnesium silicates, and silica crystals, all components of talcum powder identified in our patients, were not found in the control population that did not use talcum powder.

DISCUSSION

This paper provides the first large case series to identify cosmetic talcum powder contaminated with asbestos as the cause of malignant mesothelioma in cosmetic talc users. In 1960, Wagner presented 33 individuals exposed to crocidolite asbestos from occupational and environmental exposures, providing the first large case series of individuals diagnosed with mesothelioma with clearly identifiable exposure to asbestos.[2] Since then, the high prevalence of idiopathic mesothelioma cases suggested other possible exposures, including exposure to asbestos contaminated talc. Like Wagner, we present 33 cases, predominantly of women, who had no known exposure to asbestos other than prolonged use of talcum powder. This is consistent with the distribution of talcum powder usage in the United Sates, with greater numbers of women using powder than men.[26] Furthermore, the six case histories detailed years or decades of talcum powder use as well as tissue analysis that showed asbestos present in either tumor tissue or lymph nodes. In all six cases, asbestos fibers consistent with those identified as contaminants in repeated laboratory testing of talcum powder samples across several institutions were identified.[20,23,33,39] Notably, the fiber types found were consistent with the types of asbestos found in talc. Amosite and crocidolite, asbestos fibers that are encountered in cases of industrial and occupational exposure, not cosmetic talcum powder,[40] were not found in any of these cases.

This paper is also the first, to the authors' knowledge, to utilize background controls for which an extensive exposure history was elicited and for which no known asbestos exposure had occurred. Background controls are the best comparison when analyzing tissue of asbestos exposed individuals however, one of the biggest challenges is to choose a population of patients with no history of environmental or occupational exposure to asbestos apart from ambient air concentration of asbestos. Previous fiber burden studies of non-occupationally exposed individuals have compared the asbestos content in their tissue to workers in the same community where asbestos mines or asbestos containing factories were

TABLE 1. Description of 33 Mesothelioma Cases

Talcum Powder Exposure

Case	Sex	Year of Diagnosis	Age at Diagnosis	Mesothelioma Site	Histology	Talcum Powder Brand	Estimated Years of Use	Occupation (s)
1*	F	2015	70†	Pleural	Epithelial	A	30	Medical technician
2*	F	2015	65	Pleural	Biphasic	C, H, V	50	Homemaker
3*	F	2014	82†	Pleural	Biphasic	C	70	Teacher
4*	F	2014	66†	Peritoneal	Epithelial	B, C	30	Hairdresser
5*	F	2015	75†	Peritoneal	Epithelial	C	25	Teacher
6*	M	2016	43	Pleural	Epithelial	D	40	Finance
7	M	2016	65	Peritoneal	Epithelial	D	62	None provided
8	M	2016	76†	Pleural	Epithelial	U	38	Accountant
9	F	2016	66†	Pleural	Epithelial	C, E	35	Hair dresser
10	F	2015	80	Pleural	Epithelial	F	30	Administrative assistant
11	F	2018	73	Pleural	Epithelial	C, V	30	Flight attendant
12	F	2017	57	Peritoneal	Epithelial	A, D, G, H, I	40	Medical technologist
13	M	2016	56	Peritoneal	Biphasic	D, I, S	15	Maintenance worker
14	M	2017	56	Peritoneal	Epithelial	D	50	Molding press operator
15	F	2016	40	Peritoneal	Epithelial	D, J	12	Retail worker
16	F	2015	30	Pleural	Epithelial	D, K, L, M	19	Retail worker
17	F	2015	80†	Pleural	Epithelial	A, C, N	40	Office worker
18	F	2015	64	Pleural	Sarcomatoid	C	40	Real Estate agent
19	F	2009	62	Pleural	Epithelial	C	15	Teacher and fitness instructor
20	F	2016	69	Peritoneal	Epithelial	D, G	30	Hair dresser
21	F	2013	34†	Peritoneal	Epithelial	C	10	Teacher
22	F	2018	59	Pleural	Epithelial	C, D	42	School custodian
23	F	2016	27	Peritoneal	Epithelial	D, O	10	Not provided
24	F	2016	38	Peritoneal	Epithelial	D, I	18	Social services
25	F	2017	64	Pleural	Epithelial	D, G, J	27	Mathematician
26	F	2016	83	Pleural	Epithelial	C, D, I	60	Not provided
27	F	2017	41	Peritoneal	Epithelial	D	30	Computer programmer
28	F	2016	79	Peritoneal	Epithelial	A, C, T,	21	Not provided
29	M	2015	46	Pleural	Epithelial	D, R, U	15	Informational technology
30	F	2016	88†	Pleural	Epithelial	A, D, C, I	80	Administrative worker
31	F	2017	53	Pleural	Epithelial	D	23	Cleaner
32	F	2017	76	Pleural	Epithelial	D, C	17	Rehabilitation coordinator
33	F	2017	46	Peritoneal	Epithelial	D	25	Clerical worker

*Tissue analysis presented done by author. Tissue analysis might have been done in some cases by other investigator, these results are not presented in this paper.
†Deceased as of writing; vital status of many individuals is currently unknown.

present.[41,42] Autopsy studies have been performed[43–45] in individuals without a specific history of workplace asbestos exposure; full exposure histories were not obtained. Langer measured asbestos fiber burdens in New York City residents with no known history of asbestos.[46] Roggli and Longo[47] measured tissue burdens for individuals who had bystander or household exposure from family members who directly worked with asbestos in their work, such as laundering clothes. However that type of exposure does not truly reflect background or "unexposed" individuals. Lee and Van Orden[32] measured background air exposure in and outside of buildings. They found short chrysotile, tremolite, and actinolite fibers, but no anthophyllite or crocidolite, and very small levels of amosite. Lee and Van Orden's results are consistent with the background asbestos fibers found in the older women the present study.[32] While fiber burden studies are rarely undertaken in the course of clinical treatment, and are used primarily for medico-legal purposes, the findings of various fibers in the lung tissues can provide guidance as to potential prior asbestos exposure, whether from occupation, residential, or para-occupational exposure to asbestos. Attention to true background rates for fiber burdens is critical.[48]

Our findings strongly suggest that asbestos exposure through asbestos-contaminated cosmetic talc explains cases once deemed idiopathic or "spontaneous," and underline the importance of

TABLE 2. Tissue Digestion of Six Mesothelioma Cases

Case	Sex	Mesothelioma Site	Asbestos Type	Site Found	Concentration (Fibers/g) (Lung, Lymph)	Limit of Detection (Lung, Lymph)	Asbestos Bodies
1	F	Pleural	Anthophyllite	Lung	3,286	1,643	0
2	F	Pleural	Anthophyllite, tremolite, actinolite	Lung, lymph node	8,625, 34,500	2,875, 11,500	0
3	F	Pleural	Tremolite	Lung, lymph node	0, 9,409	6,900, 9,409	0, 409
4	F	Peritoneal	Chrysotile	Peritoneum	920	920	0
5	F	Peritoneal	Anthophyllite	Lymph node	20,700	10,350	0, 0
6	M	Pleural	Anthophyllite, tremolite	Lymph node	17,250	3,450	0

TABLE 3. Current Levels of Asbestos Fiber Burden Observed in Digests of Tissue From Autopsy and Surgical Population With no History of Asbestos Exposure (Controls)

Tissue Type	N	Asbestos Type	Mean (Fibers/Gram Wet Weight)*	Range (Fibers/Gram Wet Weight)
Lung tissue	35	Chrysotile	892	0–30,000
		Tremolite	84	0–1,552
		Chrysotile and tremolite	35	0–1,208
		Asbestos bodies	<1 bodies/gram wet weight	0–6
Paratracheal or parachronchial lymph node tissue	35	Chrysotile	72	0–1,1035
		Tremolite	29	0–552
		Chrysotile and tremolite	24	0–828
		Asbestos bodies	<1 bodies/gram wet weight	0–5
Peritoneum + gynecological tissue	10	Chrysotile	0	0
		Tremolite	0	0
		Chrysotile and tremolite	0	0
		Asbestos bodies	0	0

*All fibers that were counted were always 1 μm or less in length.

collecting detailed exposure histories that incorporate these findings in patients presenting with mesothelioma. Several factors may hinder the collection of comprehensive exposure histories among individuals diagnosed with mesothelioma. Minimal training in occupational medicine and exposure taking practice among medical students may contribute to a lack of or incomplete exposure history elicitation on the part of clinicians.[49,50] Secondly, long latency periods between exposure and illness pose a challenge both to individual recall as well the ability to establishing causality. Due to the relatively short period between diagnosis and death among mesothelioma patients, patients are often too ill or are deceased before being able to provide a full history. Furthermore, though the presence of asbestos in talc and talcum powder was first discussed in the scientific literature in the 1940s, individuals may not be aware that the products they used contained asbestos. Few clinicians are aware that this is a potential exposure. Typically, patients with mesothelioma will be simply asked whether they worked with or around asbestos, rather than being providing with a listing of potential sources of the types of exposure in which one might encounter asbestos. Cases of mesothelioma among hairdressers characterized as idiopathic also underscore the contribution of an incomplete exposure history; the potential failure to identify the use of talcum powder exposure in their work would prevent the linking of occupational exposure to asbestos to their mesothelioma. In our paper, there were three female hairdressers who regularly used talcum powder in their work. It was unclear from any of the histories noted in the medical records that these women were asked if they used talcum powder as part of the hair cutting process. In a report from the National Mesothelioma Registry of Italy, staff noted a cluster of mesothelioma due to "unknown exposure" among hairdressers, but only examined hairdryer use as a potential exposure. There was no discussion of the occupational use of talcum powder.[51] However, McDonald et al,[52] noted that a barber's occupational exposure to asbestos to talc could explain the increased finding of tremolite in the individual's lung fiber burden.

The case series presented should be understood in the context of its limitations. Data were obtained from medication records and transcripts of depositions, rather than structured, in-person interviews. However, the information solicited during the course of the patients' depositions were thorough, and included exhaustive questioning about alternative sources of asbestos exposure, including household exposure, exposures from external industrial sources, occupational exposure, and potential exposure from family members. While deposition testimony is by definition self-report, depositions were given under oath and the potential for recall bias noted would be presented whether patients completed a structured interview or were asked questions during sworn testimony. Furthermore, the utilization of medical records allowed the authors to corroborate important medical information and confirm the pathological diagnosis.

In March 2019 the Federal Drug Administration (FDA) released a statement as an update to their 2017 finding, confirming asbestos contamination of certain cosmetic products marketed and sold to young girls and outlining new steps to work with manufacturers to ensure the safety of their products.[53] While such public acknowledgment of the potential for asbestos contamination in cosmetic talc marks an important turning point, manufacturers are not legally obligated to register cosmetic products with the FDA. The results of this study coupled with the widespread use of such products[26] underline the continued risks posed to consumers through common household and cosmetic products. While these products remain unregulated and on the shelves, the use of talcum powder must be incorporated into standard exposure history practice in order to promote earlier detection of asbestos related disease among non-occupationally exposed individuals. This paper provides evidence that mesothelioma cases once considered idiopathic may be attributable to asbestos-contaminated cosmetic talcum powder usage and that the elicitation of a history of such usage is imperative to obtaining a full exposure history in all patients presenting with mesothelioma.

REFERENCES

1. Straif K, Benbrahim-Tallaa L, Baan R, et al. A review of human carcinogens–Part C: metals, arsenic, dusts, and fibres. *Lancet Oncol*. 2009;10:453–454.
2. Wagner JC, Sleggs CA, Marchand P. Diffuse pleural mesothelioma and asbestos exposure in the North Western Cape Province. *Occup Environ Med*. 1960;17:260–271.
3. Britton M. The epidemiology of mesothelioma. *Semin Oncol*. 2002;29:18–25.
4. Iwatsubo Y, Pairon JC, Boutin C, et al. Pleural mesothelioma: dose-response relation at low levels of asbestos exposure in a French population-based case-control study. *Am J Epidemiol*. 1998;148:133–142.
5. Agudo A, González CA, Bleda MJ, et al. Occupation and risk of malignant pleural mesothelioma: a case–control study in Spain. *Am J Ind Med*. 2000;37:159–168.
6. Magnani C, Agudo A, González CA, et al. Multicentric study on malignant pleural mesothelioma and non-occupational exposure to asbestos. *Br J Cancer*. 2000;83:104.
7. Rödelsperger K, Jöckel K-H, Pohlabeln H, Römer W, Woitowitz H-J. Asbestos and man-made vitreous fibers as risk factors for diffuse malignant mesothelioma: Results from a German hospital-based case-control study. *Am J Ind Med*. 2001;39:262–275.

8. Lacourt A, Gramond C, Rolland P, et al. Occupational and non-occupational attributable risk of asbestos exposure for malignant pleural mesothelioma. *Thorax*. 2014;69:532–539.
9. Markowitz S. Asbestos-related lung cancer and malignant mesothelioma of the pleura: selected current issues. *Semin Respir Crit Care Med*. 2015;36:334–346.
10. Doll R. Mortality from lung cancer in asbestos workers. *Br J Ind Med*. 1955;12:81–86.
11. Marinaccio A, Corfiati M, Binazzi A, et al. The epidemiology of malignant mesothelioma in women: gender differences and modalities of asbestos exposure. *Occup Environ Med*. 2017;75:254–262.
12. Lemen RA. Mesothelioma from asbestos exposures: epidemiologic patterns and impact in the United States. *J Toxicol Environ Health Part B*. 2016;19:250–265.
13. Henley SJ, Larson TC, Wu M, et al. Mesothelioma incidence in 50 states and the District of Columbia, United States, 2003-2008. *Int J Occup Environ Health*. 2013;19:1–10.
14. Mazurek JM. Malignant mesothelioma mortality—United States, 1999-2015. *MMWR Morb Mortal Wkly Rep*. 2017;66:214–218.
15. Porro F, Patton J, Hobbs A. Pneumoconiosis in the talc industry. *Am J Roentgenol*. 1942;47:507.
16. Hopkins O. A report on the asbestos, talc, and soapstone deposits of Georgia; 1948.
17. van Horn E. Talc deposits of the Murphy marble belt; 1948.
18. Paoletti L, Caiazza S, Donelli G, Pocchiari F. Evaluation by electron microscopy techniques of asbestos contamination in industrial, cosmetic, and pharmaceutical talcs. *Regul Toxicol Pharmacol*. 1984;4:222–235.
19. Rohl AN, Langer AM. Identification and quantitation of asbestos in talc. *Environ Health Perspect*. 1974;9:95–109.
20. Rohl AN, Langer AM, Selikoff IJ, et al. Consumer talcums and powders: mineral and chemical characterization. *J Toxicol Environ Health*. 1976;2:255–284.
21. Kleinfeld M, Messite J, Langer AM. A study of workers exposed to asbestiform minerals in commercial talc manufacture. *Environ Res*. 1973;6:132–143.
22. Luckewicz W. Differential thermal analysis of chrysotile asbestos in pure talc and talc containing other minerals. *J Soc Cosmet Chem*. 1975;26:431–437.
23. Gordon RE, Fitzgerald S, Millette J. Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women. *Int J Occup Environ Health*. 2014;20:318–332.
24. Longo DL, Young RC. Cosmetic talc and ovarian cancer. *Lancet*. 1979;314:349–351.
25. Cralley LJ, Key MM, Groth DH, Lainhart WS, Ligo RM. Fibrous and mineral content of cosmetic talcum products. *Am Ind Hyg Assoc J*. 1968;29:350–354.
26. Simmons. U.S. Brands of body and baby powder used 2017 | Statistic. Statista. Available at: https://www.statista.com/statistics/275421/us-households-brands-of-body-and-baby-powder-used/. Accessed February 21, 2018.
27. Camiade E, Gramond C, Jutand M-A, et al. Characterization of a French series of female cases of mesothelioma. *Am J Ind Med*. 2013;56:1307–1316.
28. Panou V, Vyberg M, Meristoudis C, et al. Malignant mesothelioma in 91 danish women: the environmental asbestos exposure. *J Clin Oncol*. 2017;35:8560–18560.
29. Lanphear BP, Buncher CR. Latent period for malignant mesothelioma of occupational origin. *JOM*. 1992;34:718–721.
30. Heller DS, Gordon RE, Westhoff C, Gerber S. Asbestos exposure and ovarian fiber burden. *Am J Ind Med*. 1996;29:435–439.
31. Wu M, Gordon R, Herbert R. Lung disease in World Trade Center responders exposed to dust and smoke-carbon nanotubes found in the lungs of WTC patients and dust samples. *Environ Health Perspect*. 2010;118:499–504.
32. Lee RJ, Van Orden DR. Airborne asbestos in buildings. *Regul Toxicol Pharmacol*. 2008;50:218–225.
33. Blount AM. Amphibole content of cosmetic and pharmaceutical talcs. *Environ Health Perspect*. 1991;94:225–230.
34. Snider D, Pfeiffer D, Mancuso J. Asbestos form impurities in commercial talcum powders. *Compass Sigma Gamma Epsil*. 1972;49:65–67.
35. Longo W, Rigler M. Supplemental Expert Report & Analysis of Johnson & Johnson Baby Powder and Valeant Shower to Shower Talc Products for Amphibole Asbestos; 2018.
36. Compton S. Investigation of Italian Talc Samples for Asbestos; 2017.
37. Longo W. Analysis of Johnson & Johnson's Historical Baby Powder & Shower to Shower Products from the 1960's to the Early 1990's for Amphibole Asbestos; 2018.
38. Abelmann A, Glynn ME, Pierce JS, Scott PK, Serrano S, Paustenbach DJ. Historical ambient airborne asbestos concentrations in the United States—an analysis of published and unpublished literature (1960s–2000s). *Inhal Toxicol*. 2015;27:754–766.
39. Investigation of Possible Asbestos Contamination in Talc Samples; 1972.
40. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Carbon Black, Titanium Dioxide, and Talc. Lyon, France: World Health Organization International Agency for Research on Cancer; 2010.
41. Dodson RF, Huang J, Bruce JR. Asbestos content in the lymph nodes of nonoccupationally exposed individuals. *Am J Ind Med*. 2000;37:169–174.
42. Dodson RF, Williams MG, Huang J, Bruce JR. Tissue burden of asbestos in nonoccupationally exposed individuals from east Texas. *Am J Ind Med*. 1999;35:281–286.
43. Churg A. Asbestos fibers and pleural plaques in a general autopsy population. *Am J Pathol*. 1982;109:88–96.
44. Warnock ML, Churg AM. Asbestos bodies. *Chest*. 1980;77:129–130.
45. Srebro SH, Roggli VL, Samsa GP. Malignant mesothelioma associated with low pulmonary tissue asbestos burdens: a light and scanning electron microscopic analysis of 18 cases. *Mod Pathol*. 1995;8:614–621.
46. Langer AM, Selikoff IJ, Sastre A. Chrysotile asbestos in the lungs of persons in New York City. *Arch Environ Health*. 1971;22:348–361.
47. Roggli VL, Longo WE. Mineral fiber content of lung tissue in patients with environmental exposures: household contacts vs. building occupants. *Ann N Y Acad Sci*. 1991;643:511–518.
48. Gordon RE. Analytic Analyses of Human Tissues for the Presence of Asbestos and Talc. In: Electron Microscopy-Novel Microscopy Trends. IntechOpen; 2019.
49. Papali A, Hines SE. Evaluation of the patient with an exposure-related disease: the occupational and environmental history. *Curr Opin Pulm Med*. 2015;21:155–162.
50. Politi BJ, Arena VC, Schwerha J, Sussman N. Occupational medical history taking: how are today's physicians doing? A cross-sectional investigation of the frequency of occupational history taking by physicians in a major US teaching center. *J Occup Environ Med*. 2004;46:550–555.
51. Carugno M, Mensi C, Sieno C, Consonni D, Riboldi L. Asbestos exposure among hairdressers. *Med Lav*. 2012;103:70–71.
52. McDonald AD, Case BW, Churg A, et al. Mesothelioma in Quebec chrysotile miners and millers: epidemiology and aetiology. *Ann Occup Hyg*. 1997;41:707–719.
53. Gottlieb S, Mayne S. Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition, on Tests Confirming a 2017 Finding of Asbestos Contamination in Certain Cosmetic Products and New Steps That FDA Is Pursuing to Improve Cosmetics Safety; 2019. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632736.htm. Accessed May 30, 2019.

EXHIBIT "2"

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION; MIDDLESEX COUNTY

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DWAYNE JOHNSON,

Plaintiff, Docket No.

v. MID-L-6651-16AS

AMERICAN INTERNATIONAL
INDUSTRIES, INC., et al.,

Defendants.

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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION; MIDDLESEX COUNTY

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MARGARET ROSE LANGLEY LASHLEY
and EDWARD GENE LASHLEY,

Plaintiffs, Docket No.

v. MID-L-7336-16AS

AMERICAN INTERNATIONAL
INDUSTRIES, INC., et al.,

Defendants.

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January 15, 2020

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Videotaped deposition of JACQUELINE MOLINE, MD, held at 175 Community Drive, Great Neck, New York, commencing at 10:00 a.m., on the above date, before Marie Foley, a Registered Merit Reporter, Certified Realtime Reporter and Notary Public.

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article are all individuals that filed lawsuits, and the reason that you're -- you know about them is because you were an expert witness in their case, right?

MS. KAGAN: Argument; foundation.

A. That is correct.

Q. So, you weren't the treating physician for any of the 33 patients that were included in your article, right?

A. Correct.

Q. Whatever information you had from your article you got from deposition transcripts and other legal documents associated with the case, right?

A. Or an in-person interview, if I had the opportunity to meet them.

Q. So, why can't you tell me whether the Bell case was one of the cases that you included in your article?

A. Because the individual names and -- are covered under research protections for confidentiality.

Q. Are covered by, I'm sorry? What

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did you say?

A. Are covered under the Institutional Review Board with respect to patient confidentiality, or individual confidentiality. Research subject confidentiality.

MS. KAGAN: I can actually shortcut this for you.

If we take a look at those two prior depositions that she noted, as well as the McClendon case, which was a Cashmere Bouquet case with your former partner Ed Slaughter. The position that Dr. Moline has taken, as well as Northwell, is that if this is information that you seek, then you're going to have to subpoena it from the hospital and the hospital's lawyers are going to deal with it. It's not something that -- that we, Simon Greenstone, or any other individual plaintiff's law firm is taking a position on. It's proprietary information that the hospital and the

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hospital's lawyers will respond to.

MR. THACKSTON: All right.

Thanks.

BY MR. THACKSTON:

Q. The information that you used to write the article was provided to you by plaintiffs' lawyers, right?

A. I don't know you're -- I don't know how you're characterizing.

Do you mean the raw data with respect to medical records and pathological diagnoses that would have come as a result or contained within the medical records?

That would have been provided through plaintiffs' lawyers, correct.

Q. And all of the information regarding the people's exposures came from either depositions in the cases or statements that they had made that were -- that reflected in their medical records, right?

MS. KAGAN: Mischaracterizes; argument.

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C E R T I F I C A T E

STATE OF NEW YORK

COUNTY OF NEW YORK

I, Marie Foley, RMR, CRR, a Certified Realtime Reporter and Notary Public within and for the State of New York, do hereby certify:

THAT JACQUELINE MOLINE, MD, the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 23rd day of January, 2020.

MARIE FOLEY, RMR, CRR

EXHIBIT "3"

Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women

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Background: Cosmetic talcum powder products have been used for decades. The inhalation of talc may cause lung fibrosis in the form of granulomatose nodules called talcosis. Exposure to talc has also been suggested as a causative factor in the development of ovarian carcinomas, gynecological tumors, and mesothelioma.
Purpose: To investigate one historic brand of cosmetic talcum powder associated with mesothelioma in women.
Methods: Transmission electron microscope (TEM) formvar-coated grids were prepared with concentrations of one brand of talcum powder directly, on filters, from air collections on filters in glovebox and simulated bathroom exposures and human fiber burden analyses. The grids were analyzed on an analytic TEM using energy-dispersive spectrometer (EDS) and selected-area electron diffraction (SAED) to determine asbestos fiber number and type.
Results: This brand of talcum powder contained asbestos and the application of talcum powder released inhalable asbestos fibers. Lung and lymph node tissues removed at autopsy revealed pleural mesothelioma. Digestions of the tissues were found to contain anthophyllite and tremolite asbestos.
Discussion: Through many applications of this particular brand of talcum powder, the deceased inhaled asbestos fibers, which then accumulated in her lungs and likely caused or contributed to her mesothelioma as well as other women with the same scenario.

Keywords: Asbestos, Talcum powder, Chamber test, TEM, SEM, EDS, SAED, Mesothelioma

Introduction

Malignant mesothelioma occurs in both the peritoneum and in the lung pleura.[1] Mesothelioma cases have been attributed to direct occupational exposure, indirect exposure and secondary exposure.[1] A higher rate of "idiopathic" mesothelioma has been reported in women, as no link between asbestos exposure and patients has been identified.[2] Previous research suggests that ovarian cancer and peritoneal mesothelioma may be directly attributed to the use of talcum powder contaminated with asbestos or from exposure to partners occupationally exposed to asbestos.[3–7] Using talcum powder in closed spaces may increase the likelihood of inhaling the powder laced with asbestos. Repeated applications increase the opportunities for inhalation and the asbestos could become concentrated in the peripheral airways and alveoli of the lungs of the talcum powder users. This has been supported by the presence of granulomas in the lungs of some talcum powder users.[8]

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In 1976, Rohl and Langer tested 20 consumer products labeled as talc or talcum powder, including body powders, baby powders, facial talcums, and a pharmaceutical talc.[6] Of the 20 products tested, 10 were found to contain tremolite and anthophyllite, principally asbestiform. The product with the highest asbestos content was the same product tested in this study. Both asbestiform anthophyllite and asbestiform tremolite were found in the Rohl and Langer tests. Given that asbestos has been determined as the primary cause of mesothelioma, it is important to note that cosmetic talc contained asbestos in the past.[6] The contamination results from the mining process, since ore specimens taken directly from the mines have repeatedly been tested and shown to contain asbestos, most often anthophyllite and tremolite but also serpentine chrysotile asbestos.[6,9,10]

In part from the review of corporate documents and the sworn testimony of those responsible for the sourcing of talc used in the products studied here, it was determined that three mines provided the raw material for use as talcum powder. The talc used by this cosmetic company that manufactured and

distributed the talcum powder was from three distinct regions: the Willow Creek mine in Southwest Montana, the Regal mine near Murphy, North Carolina, and imported talc from the Val Chisone region of the Italian Piedmont.[11–16] The specific geology of talc is an important indicator of whether a talc source may be contaminated with asbestos. These three mines all contained asbestos fibers; anthophyllite, and tremolite.[11–18] The Val Chisone talc from Italy was studied by Pooley in 1972.[18] Mine sample had intergrowths with serpentine-type, chrysotile asbestos along with tremolite and anthophyllite asbestos. The talc from Italy was named 'American Ground Italian' and designated as AGI 1615.[19–21] This talc was diluted with a talc from another source to make it acceptable based on X-ray diffraction (XRD) protocols. However, it contained asbestiform tremolite and anthophyllite.[22]

In this study, three laboratories analyzed a specific brand of talc from more than 50 containers of this cosmetic talcum powder product of different sizes and colors, produced over a 50-year time span to determine the presence of asbestos. The authors conducted independent product testing in unassociated laboratories in North Carolina, Georgia, and New York. A fourth laboratory, which also tested this product, will herein be referred to as Laboratory D. The lung and lymph node tissues from a woman who died from mesothelioma and testified to only using this specific brand of talcum powder were analyzed for the presence of asbestos and talc. This is the first report that explores the hypothesis that a specific brand of talcum powder coming from asbestos contaminated mines can find its way into the finished product that can be inhaled during use and cause or contribute to the development of mesothelioma

Materials and Methods

Laboratory A: product testing

In Laboratory A, over 50 containers of this particular brand of talcum powder were acquired from a variety of sources for bulk testing. Some of the containers were purchased online, while others were provided directly from the manufacturer. All of the containers were verified to be the correct brand and product.

Laboratory A tested talcum powder from each of the 50 samples using transmission electron microscope (TEM) methods. The procedure for testing by Lab A was as follows: 0.01 g of talcum powder was removed from its vial and suspended in 1 ml of distilled water with one to two drops of ethanol by brief sonication. From this suspension, 10 µl aliquots were removed and placed on a series of five formvar-coated nickel grids (100 grid openings each). In some five grids from the same 0.01 g sample of powder. The drops were allowed to dry in a covered Petri dish. The grids were then examined and analyzed with a Hitachi H-7000 STEM equipped with an Evex energy-dispersive spectrometer (EDS), for elemental composition and relative amounts of elements. The microscope was equipped with a tilt stage and a rotary specimen holder, which was employed with selected-area electron diffraction (SAED) analyses, as described below. Structures seen as fibers measuring at least five micrometers in length with aspect ratios of 5 : 1 or greater were analyzed to determine if they were regulated asbestos mineral fibers. We used EDS to chemically establish the presence of asbestos fibers and the crystalline structure was assessed using SAED. All 100 grid openings were observed and analyzed on each of the five grids for each product sample (at least 500 grid openings per sample analyzed).

Analyses were performed using a modification of the techniques described by Yamate *et al.*, and similarly adopted techniques used by the Environmental Protection Agency (EPA), American Society for Testing and Materials (ASTM), and International Organization for Standardization.[23–26] All techniques required the use of a TEM equipped with an EDS system. Only in Yamate level III is the tilt and rotary stage optional to perform advanced SAED zone axis analysis. Yamate *et al.* stated that zone axis diffraction analysis is useful in differentiating between otherwise unidentifiable fibers.[23] In the Laboratory A analysis, zone axis analyses were not necessary as the identified amphiboles clearly demonstrated that they were asbestiform tremolite and anthophyllite confirmed by morphology, EDS chemistry, and characteristic 5.3 Å inter-row repeats on diffraction without tilting. Both asbestiform and non-asbestiform particles and fibers were present. However, in most cases this manuscript will refer to asbestiform fibers and state when they are tremolite, anthophylite, or chrysotile type asbestos. A non-asbestos tremolite, anthophylite will not be referred to as asbestos.

To calculate the fiber concentrations per gram of talcum powder, we first determined the number of asbestos fibers on average per grid opening. This number was multiplied by 552. The product of that equation was multiplied by 100, and then divided by 0.01 to yield the fibers/gram talcum powder value. The constant, 552, is the number of grid opening areas on the entire grid. One hundred is the number of 10 µl drops in 1 ml that the talcum powder was dispersed and the 0.01 was the weight of the talcum powder dispersed. Quality control procedures, which included testing of blanks from water, working in a

Figure 1 Pouring of powder into hands in glovebox.

sample at a time ensured that no laboratory contamination of samples.

Laboratory B: asbestos releasability testing

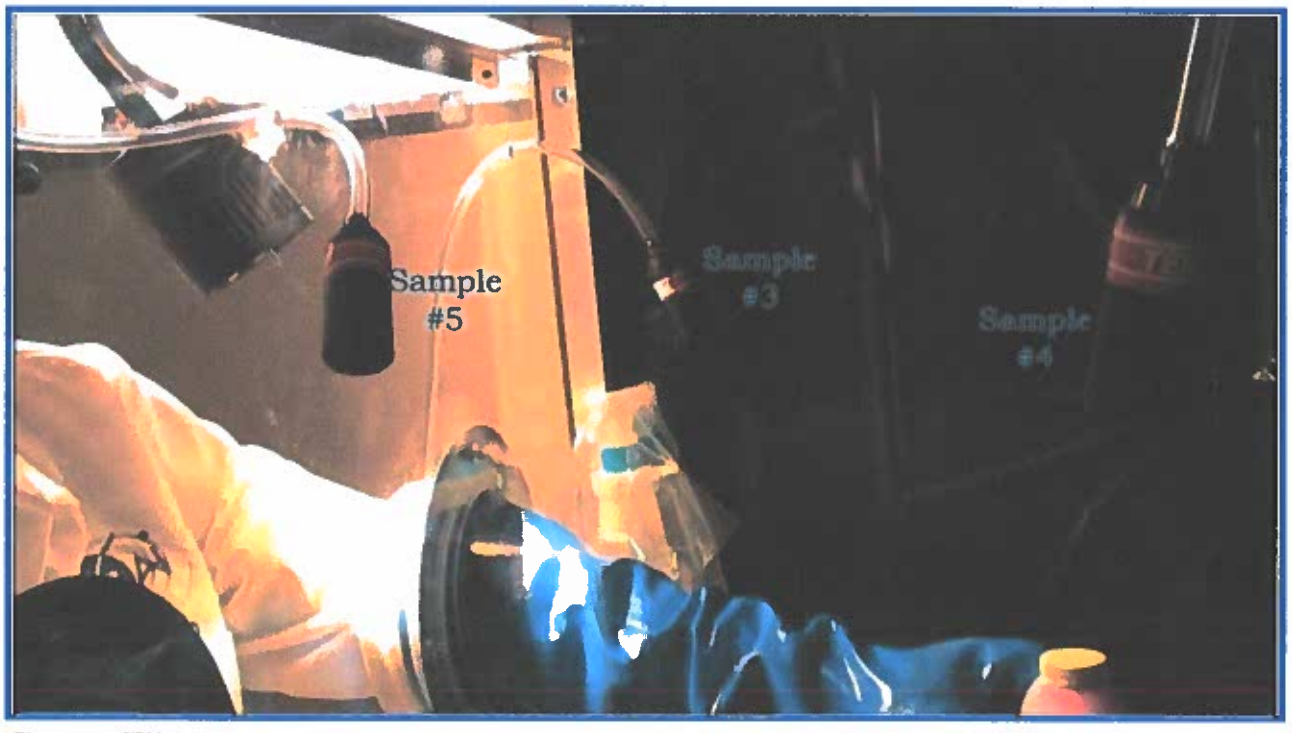
To determine if the user could inhale asbestos during a talcum powder application, Laboratory B assessed asbestos releasability by air sample. Air samples were generated during simulation in a glove box, consistent with normal product use in a controlled environment. These three samples included the same samples tested by Laboratory A. Environmental and personal air samples were collected using standard airborne asbestos techniques, using high-volume air pumps for environmental (stationary) samples inside and outside of the controlled area, and low-volume air pumps for personal samples taken at a distance comparable to the breathing zone of the person simulating application. Standard TEM 385 mm^2 effective filter area 25 mm cassettes with 0.45 µm MCE filters were used on the flow-calibrated high (7–12 l/min) and low volume (1–4 l/min) air pumps (Figs. 1 and 2).

The resulting air samples were analyzed for airborne asbestos following the analytical procedures described in the U.S. Environmental Protection Agency Code of Federal Regulations *40 CFR part 763, subpart E, Appendix A* — AHERA for direct preparation of MCE filters.[24] All final analyses by Laboratory B were conducted on a JEOL 2000FX TEM equipped with an energy-dispersive X-ray analyzer detector and SAED at magnifications up to × 50 000, using the fiber counting criteria specified by Yamate *et al.*'s protocols.[23]

Laboratory C: product bulk testing and bathroom-sized chamber releasability

Bulk methods

Laboratory C examined nine samples under an Olympus SZ-40 stereomicroscope at magnifications from × 7 to × 40. Portions of the particulate found in the sample were mounted in Cargille refractive index liquids for analysis by polarized light microscopy (PLM) using an Olympus BH-2 PLM with a magnification range from × 100 to × 1000. The PLM analysis followed the procedures for bulk analysis of building materials described by the US EPA in 1993.[24] Characterization of the fibers was performed using a Philips EM420 100 kV TEM equipped with an Oxford INCA EDS x-ray analysis system and capable of SAED work involving tilting of amphibole fibers. Zone axis determinations were also conducted. We used TEM asbestos fiber counting criteria of fibers greater than 0.5 µm in length with at least a 5 : 1 aspect ratio as described in Asbestos Hazard Emergency Response Act (AHERA) and ASTM methods: D6281, D5755,



D5756, and D648.[24–28] Data were recorded using the ASTM D6281 format. XRD analysis was performed by an outside laboratory (DCM Science Laboratory, Inc., Wheat Ridge, CO, USA) scanning over a range of 3–45° 2Θ using 40 kV, 25 mA Cu K_α radiation. Mineral phases were identified with the aid of computer-assisted programs accessing a CD-ROM powder diffraction database.

Air testing

Tests to determine airborne levels of asbestos fibers resulting from application of this brand of talcum powder were performed in a testing chamber. The chamber was built to match the bathroom of the patient that used this brand of cosmetic talc. Her bathroom was measured at 7 feet, 9 inches high by 5 feet by 4 feet, 1 inch. All talc products used in these chamber tests had previously been tested in Laboratories A, B, or both.

Air test — shaker container

Using Personal Protective Equipment, a volunteer applied one of the bulk tested cosmetic talcum powders to his body using a shaker container. This particular talcum powder contained approximately 0.1% by weight and approximately 18 million anthophyllite asbestos fibers per gram. The container was weighed before and after the testing to determine the approximate weight of material applied. The talcum user wore a respirator and a bathing suit. The volunteer twisted the top of the container and shook material onto his hand. He applied the talc under his arm and around the shoulder and upper arm area. He then shook the talcum powder onto his other hand and applied it to the other underarm, shoulder and upper arm area. He shook out additional material and applied it to his neck and upper torso. He shook out and applied material two more times for a total of five applications. The total talcum application time was approximately 1 min and amounted to 0.37 g of the talcum powder. Two air samples were collected in the applier's breathing zone at 0.5 l per minute (lpm) and two additional air samples were collected in the breathing zone at 1.0 lpm with commercial open-face air cassettes. The five-minute sampling time included the application time and a waiting period. The bystander in the test chamber had two air cassettes in his breathing zone for the five-minute period including application and the additional waiting time. The bystander wore a respirator and full protective clothing. These air samples were collected at rates of one and 2 lpm. No activities were conducted during the waiting period other than checking the pumps and cassettes. The air filters and two additional blank filters were analyzed by phase contrast microscopy (PCM) using National Institute for Occupational Safety and Health (NIOSH) Method 7400.[29] Two air samples and two blanks were also analyzed by NIOSH Method 7402 via transmission electron microscopy to determine the percentage of asbestos fibers among the fibers counted by PCM.[29] An air sample collected from within the test chamber before the study was analyzed by a more sensitive TEM procedure following the EPA AHERA method.[24]

Air testing puff applicator

In this test, a volunteer applied a different cosmetic talcum powder sample using a puff applicator. This particular talcum powder contained approximately 0.05% anthophyllite asbestos (approximately 70 million asbestos fibers per gram). The container was weighed before and after the testing to determine the approximate weight of material applied. The talcum user wore a respirator and a bathing suit. The talc user opened the puff container and applied the talcum powder as described above only this time with a powder puff. He then repeated the process for a total of six applications. The talcum application time was approximately 1 minute. Two air samples were collected in the applier's breathing zone at 0.5 lpm for a sampling period of 4 minutes. One air sample was collected for a shorter period (3.3 minutes) that included the application period. Another air sample was to be collected after the application period but this sample was voided because the volunteer hit the air cassette and the cassette fell off the vacuum hose. The bystander in this test followed the same protocol as described above. Both air samples were collected at a rate of 0.5 lpm. No activities were conducted during the waiting period other than checking the pumps and cassettes. The air filters and two additional blank filters were analyzed by PCM using NIOSH Method 7400 as described above.[29] One air sample and two blanks were also analyzed by NIOSH Method 7402 via TEM to determine the percentage of asbestos fibers among the fibers counted by PCM.[30] An air sample collected from within was tested as described above by EPA AHERA method.[24]

Human Tissue Analysis

TEM

Tissue samples from a woman with no other known exposure to asbestos other than her use of the product tested was supplied to Laboratory A. Human tissue analysis was performed according to the techniques described in Wu *et al.*[29] Lung and lymph node tissue was received fixed in formalin. Half of the tissue was removed from the lung and the lymph node tissue. Two grams of lung tissue were divided twice. The two halves of the lymph node weighed 0.16 g together. The two specimen types were separated throughout the study. The tissue from

hydroxide (KOH) for approximately hour at 60°C. The dissolved lung and lymph node material was then centrifuged in a high-speed centrifuge to separate the inorganic material from the dissolved organic tissue. The solute material containing the dissolved organic material and KOH was removed and distilled water was added. The inorganic material was re-suspended in the water by brief sonication. The material was re-centrifuged and the process of washing the inorganic material was performed five times. After the fifth wash, the distilled water was removed and replaced with 10 ml of fresh distilled water and the inorganic material was re-suspended by brief sonication. Ten microliter samples were removed from the suspension and placed on formvar-coated nickel grids on a metal mesh in a covered glass Petri dish to dry. Five grids were initially prepared and an additional set of five grids was prepared for each tissue type for a second analysis. The dried grids were observed with a transmission electron microscope. Four hundred grid openings on at least four grids were analyzed, and a fifth grid was used if grid openings were broken in the initial four examined grids. The fiber concentrations per gram wet weight lung or lymph node tissues were calculated from the number of fibers observed, the area analyzed, the aliquot ratio, and the total weight of the tissue sample digested.

Light microscopy

Tissue sections

Small lung tissue samples were put into 10% phosphate-buffered formalin and processed for embedding in paraffin. Five micrometer paraffin sections were cut, mounted on glass slides and stained with hemotoxylin, eosin, and an iron stain. The tissue was evaluated for the presence of altered morphology and/or ferruginous bodies; two characteristics often seen in lung tissues that are a byproduct of iron-rich protein deposits on asbestos fibers resulting from macrophage frustrated phagocytosis.

Digested lung and lymph node tissue

Two hundred and fifty microliters of digested lung and lymph node material suspension used for TEM analyses was placed in a cytocentrifuge and the slides were cover slipped and observed by phase contrast light microscopy. The entire area was counted for ferruginous bodies and calculated back to the weight of the tissue to determine the concentration of bodies per gram of wet weight tissue.

Scanning electron microscopy (SEM)

SEM samples were prepared by taking 250 µl of the suspended inorganic material used for the TEM and light microscopy analyses and placed on a 0.1 µm pore size Nucleopore filter mounted on a carbon [illegible] was allowed to dry in a covered Petri dish. The stub was then coated with vaporized carbon and observed with a Hitachi S-4300 field emission scanning electron microscope equipped with an Evex EDS system. The entire filter sample surface was scanned for fibers and asbestos bodies.

Results

All three laboratories confirmed in multiple tests the presence of asbestiform anthophyllite and asbestiform tremolite in the talcum powder products, just as had been found and described by Rohl and Langer over three decades ago.[6]

Initial bulk analyses of 50 samples of this product in Laboratory A showed that all of the samples contained asbestos fibers. Eighty percent contained only anthophyllite asbestos, 8% only tremolite asbestos, 8% anthophyllite and tremolite asbestos and 4% anthophyllite, tremolite, and chrysotile asbestos. The range in asbestos concentrations of fibers >5 µm in length were calculated to be, at a minimum, between 1840 and 1 104 000 fibers per gram of talcum powder. More than 80% of the tested cans and plastic containers contained over 10 000 asbestos fibers/gram of talcum powder. Four of the containers had less than 5000 fibers per gram and six containers had more than 250 000 fibers per gram. However, it should be noted that there were many asbestos fibers that also had aspect ratios less than 8:1. These fibers were generally found to be shorter than 5 µm and were noted, but not counted in the original product testing or in the lung and lymph node tissue testing by Laboratory A. There were also a number of fibrous talc particles that were easily distinguishable from asbestos by morphology. If there was a question regarding their identity, both EDS and SAED were employed to recognize such fibers as talc. All the fibers that were actually counted in bulk and tissue preparations were 5 µm or greater in length, with aspect ratios for the most part greater than 10:1. The majority of asbestos structures counted demonstrated aspects ratios >15:1, with many >20:1. A minimum of four fibers was identified in each sample, making the concentration determinations of asbestos statistically significant and reproducible.

Laboratory C. using PLM, TEM, and XRD, tested nine samples of the specific brand of talcum powder described above. Generally, the PLM analysis showed that the samples contained both platy and fibrous talc, less than 1% by volume of the PLM visible amphibole fibers and some quartz. The majority of the PLM amphibole particles had low aspect ratios (length to width) but some were >10:1. By XRD, one of the talcum powder samples was [illegible]

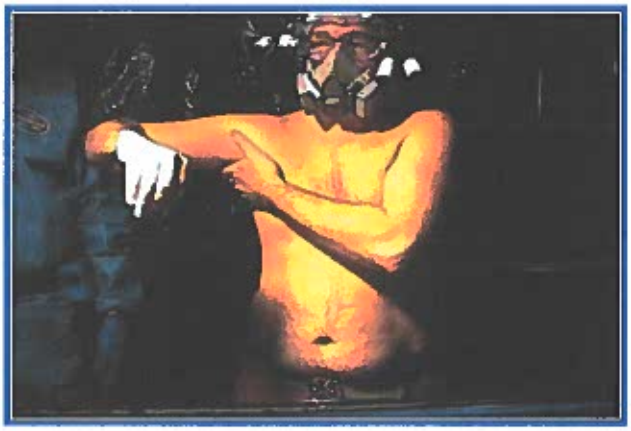


Figure 3 Application of powder from shaker in bathroom-sized chamber.

Figure 4 Application with powder puff in bathroom-sized chamber.

minerals were detected in the other eight samples by XRD. The XRD detection limit was approximately 2% by weight. In TEM analysis, all nine samples were positive for amphibole asbestos (primarily anthophyllite), and were confirmed with zone-axis electron diffraction measurements. At least five asbestos fibers per sample were recorded in each sample, with concentrations ranging from 0.004 to 0.9% by weight and from 3 to 200 million asbestos fibers per gram of fibers greater than 0.5 μm in length with at least a 5 : 1 aspect ratio.

Air monitoring

Releasability of asbestos into the air from the products was assessed by glove box simulation testing by Laboratory B, and by full chamber testing by Laboratory C. In a manner consistent with methods used by the EPA, NIOSH or ASTM, study product body powders and dusting powders were applied hand to hand and hand to arm. Consistent with bulk testing results, anthophyllite and tremolite asbestos was repeatedly found in the air tests resulting from these simulations (Figs. 6–8).

Shaker container test

The shaker application test used 0.37 g of talcum powder (Fig. 3). For the talc user, the average PCM fiber concentration in his breathing zone during application was 4.8 F/cc (3.1, 7.3, 3.9, and 4.9 F/cc). The asbestos to total fiber percentage as determined by TEM was 40%. Therefore, the asbestos concentration in the breathing zone of the talc user during application was 1.9 F/cc. For the bystander the PCM fiber concentration was 1.35 F/cc (0.9 and 1.8 F/cc) and the TEM derived percentage of asbestos was 35%, which results in a bystander asbestos concentration of 0.5F/cc. No asbestos fibers were found in the sample collected in the chamber before the testing or in the blank filters.

Puff application

The puff application test used 6.25 g of talcum

PCM fiber concentration in his breathing zone during the 5-minute sampling period was 20 F/cc (23.6 and 16.5 F/cc). The asbestos to total fiber percentage as determined by TEM was 21%. Therefore, the asbestos concentrations in the breathing zone of the talcum powder user were 5 and 3.5 F/cc. The short term sample in the breathing zone of the applier had a PCM value of 60 F/cc. Using the TEM-derived percentage of asbestos of 10%, result for the short-term sample was an asbestos concentration of 13 F/cc. For the bystander, the PCM fiber concentration was 11.7 F/cc (13.7 and 9.7 F/cc). Using the minimum TEM-derived percentage of asbestos of 36% results in a bystander asbestos concentration of 4.9 and 3.5 F/cc. No asbestos fibers were found in the sample collected in the chamber before the testing or in the blank filters.

The tests performed independently by Laboratory C using a bathroom-sized room confirmed the findings for asbestos fiber release found by Laboratory B's glovebox testing. Samples showed that significant concentrations of anthophyllite, tremolite, and occasionally chrysotile asbestos were released in the simulated application of several iterations of the products. This confirmed not only

Figure 5 Application with a powder puff in bathroom-sized

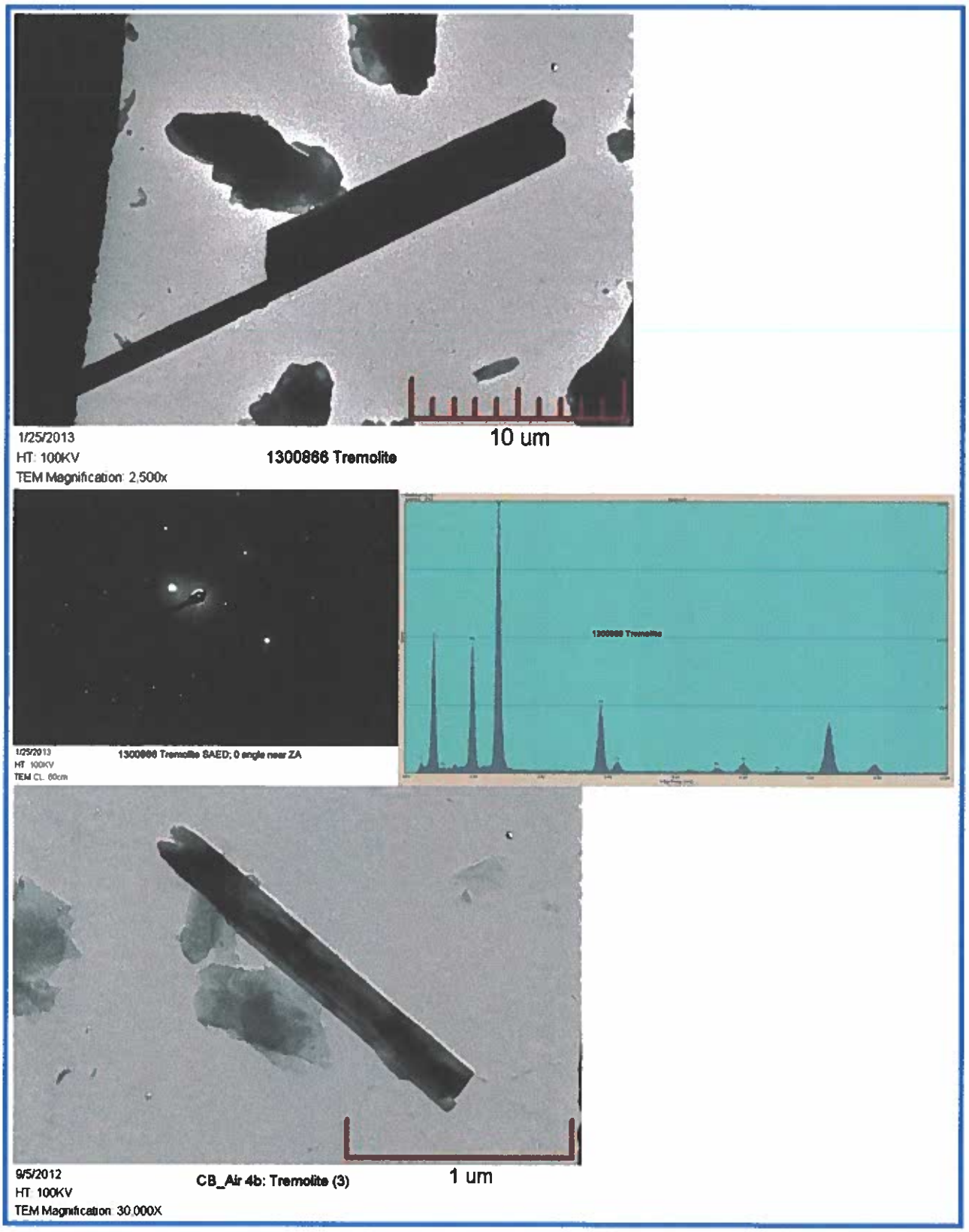


Figure 6 Tremolite asbestos from TEM analysis of releasability air testing of product (images, EDS, and SAED).

the presence of asbestos in the talcum powders, but also that the asbestos contained in the friable powders was easily aerosolized in a manner consistent with the products intended use; confirming the hypothesis that the cosmetic powders are capable

Human tissue analysis

Electron microscopic analysis of the lung tissue revealed amphibole type asbestos fibers in a calculated concentration of 1380 and 4150 fibers per gram wet weight, respectively, with a limit of detection of

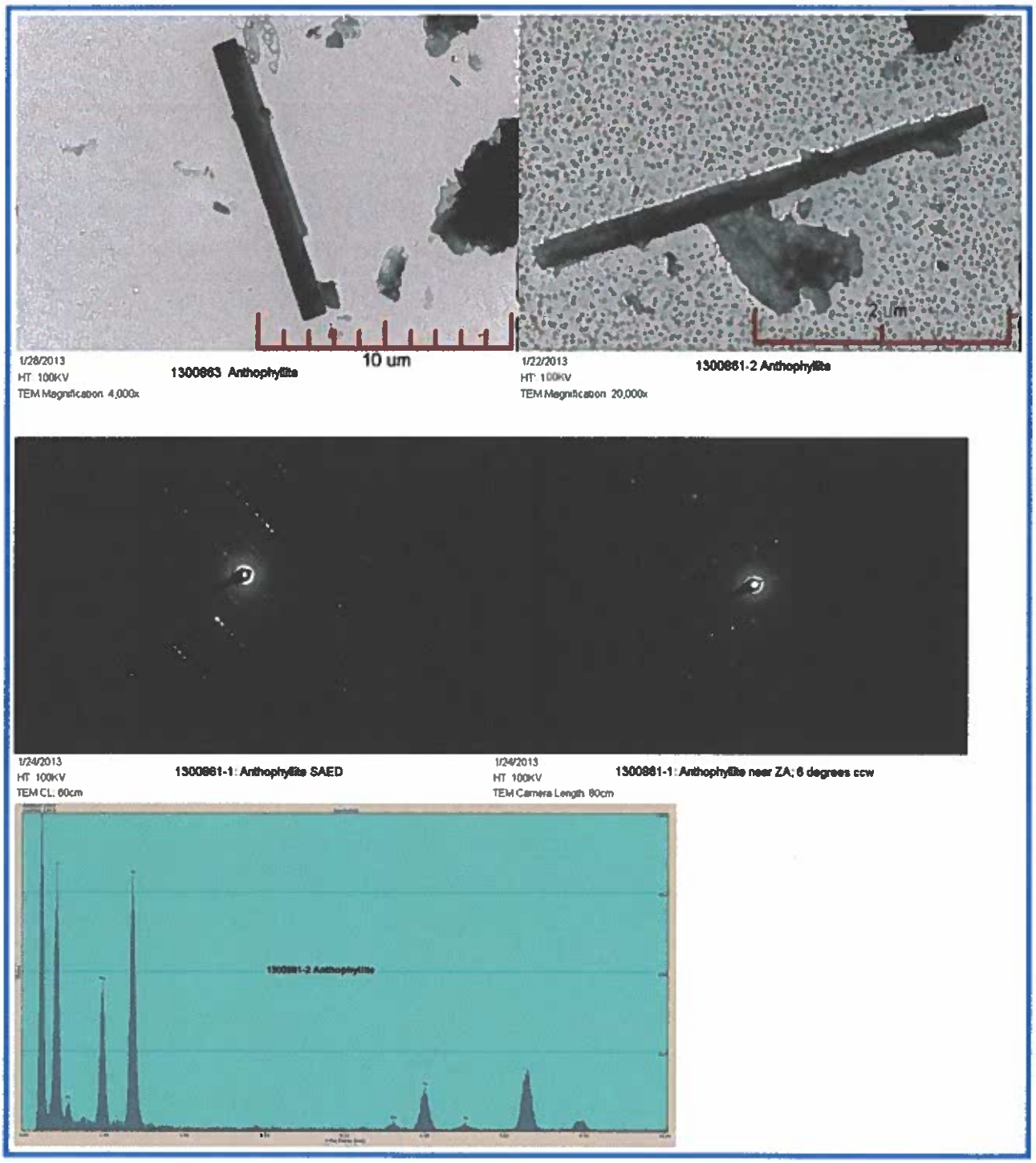


Figure 7 Anthophyllite asbestos from TEM analysis of releasability air testing of product (images, EDS, and SAED).

were 5 μm or greater in length and had aspect ratios of 20 : 1 or greater. The amphiboles were identified by EDS and SAED analysis as anthophyllite (Fig. 9) and tremolite (Fig. 10) asbestos. The asbestos fibers were seen in a ratio of 1 : 1 and 2 : 1, respectively (anthophyllite/tremolite). There were many anthophyllite and tremolite asbestos fibers less than 5 μm in length that were not counted. The majority of these smaller asbestos fibers were of the anthophyllite type. Light microscopic analysis of the cytocentrifuge preparation revealed a calculated concentration of 140 asbestos bodies per gram wet weight of lung tissue by phase contrast light microscopy in both samples.

Electron microscopic analysis of the lymph node tissue revealed amphibole asbestos fibers in a calculated concentration of 12 738 fibers per gram wet weight, with a limit of detection of 2123 fibers per gram wet weight. All counted fibers were at least 5 μm in length with aspect ratios of 10 : 1 or greater. The amphiboles were identified by EDS and SAED analysis as anthophyllite and tremolite and they were seen in a ratio of 5 : 1 anthophyllite/tremolite. There were many anthophyllite and tremolite fibers less

Figure 8 Chrysotile asbestos from TEM analysis of releasability air testing of product (image and SAED).

than 5 μm in length that were not counted. We also observed but did not count tremolite cleavage fragments. Light microscopic analysis of the cytocentrifuge preparation revealed a calculated concentration of 92 asbestos bodies per gram wet weight of lymph node tissue by phase contrast light microscopy (Fig. 11).

Histological sections of the tissue showed focal areas of mild parenchymal fibrosis and a more generalized pleural fibrosis. Although many ferruginous bodies were identified in the cytocentrifuge preparation, most were relatively small and not seen in the H&E-stained paraffin sections. These macrophages were clustered and contained a combination of fibrous and platy talc and small asbestos bodies.

In addition to the fibrous and platy talc described above, other inorganic materials were seen. Aluminum silicates and magnesium aluminum silicates in both fibrous and platy form were identified. We elected not to count these fragments. Their presence supports the hypothesis that the lung and lymph node samples match findings from the tested talcum powder.

The two analyses performed on the lung tissue were from two separate tissue digestions. The second saved from the original half of the tissue retained by Laboratory A. The results proved to be completely reproducible with no finding of any additional fiber types other than those reported above.

Confirmation of interlaboratory analyses

After several years of independent testing in separate laboratories, the authors became aware of one another's work through litigation. The finding that this historic brand of cosmetic talcum powder contained asbestos fibers with generally the same morphological and chemical assemblage was confirmed. A fourth laboratory (Laboratory D) tested many of the same samples, but did not report asbestos findings. Owing to the inconsistency with the other laboratories, re-examination of results from Laboratory D was warranted.

Two of the three authors of this study went to the Laboratory D and were supplied with the prepared filters on TEM grids or SEM stubs previously analyzed by Laboratory D. They were also supplied with both TEM and SEM microscopes to re-analyze the specimens, along with data and locator sheets, allowing for the same grid openings and areas to be observed as in the initial analyses.

Reanalysis of subject product samples

One author re-analyzed the TEM preparations of 20 study products of talcum powder prepared by Laboratory D. Asbestos structures were found in the re-analysis, some of which were named in the original analysis as cleavage fragments, intergrowths, or fibrous talc rather than as asbestos. Although the author–reviewer agreed with many of the non-asbestos fibers identified, he concluded the original analyses were incomplete. Additional analyses by the author–reviewers showed some of the incompletely analyzed fibers to be asbestos. In other cases, asbestos found on re-analysis was located on areas of the filter where no fibers were recorded in the original bench sheets or reports. In some instances, the overall distribution of particulates on the preparations was inhomogeneous, in contrast with the method of choosing grid openings for the original analysis by skipping every other opening in a "checkerboard" fashion. Furthermore, the methods named on the analytical count sheets were not the same as the methods cited in the reports from Laboratory D.

Laboratory D reported no asbestos fibers in the 20 samples analyzed. In contrast, asbestos fibers were identified in all 20 of the same products in Laboratory A and in 16 of 20 products tested by Laboratory B. In the re-analysis of those same 20 samples originally analyzed by Laboratory D via TEM, eight were found to contain asbestiform anthophyllite, six asbestiform tremolite, and two were found to contain chrysotile fibers. These

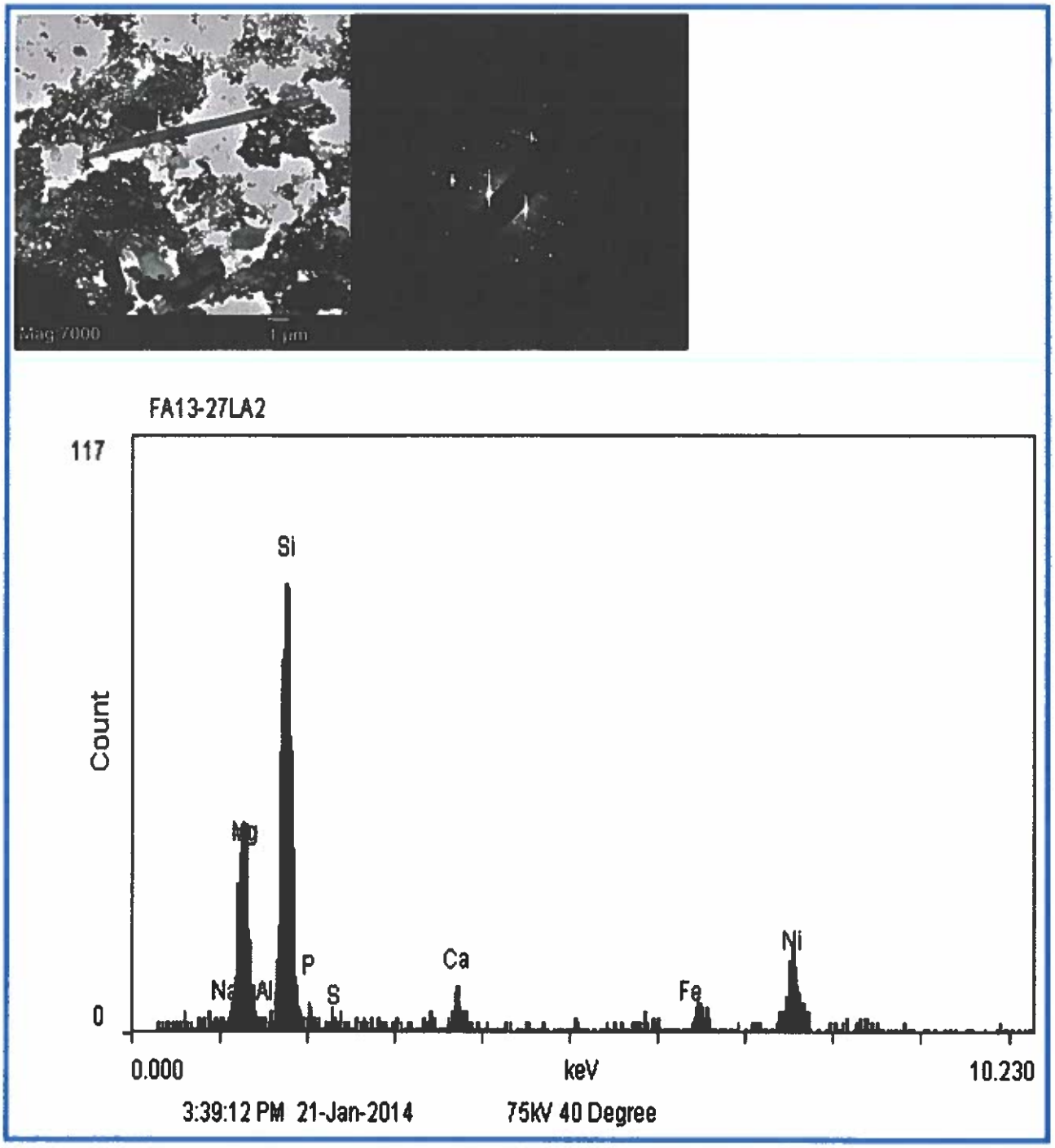


Figure 9 This asbestos fiber is a representative sample removed from the lung tissue of the patient exposed to cosmetic talcum powder. Anthophyllite asbestos fiber is observed and its SAED pattern is demonstrated beside it with the EDS spectra.

complete replication of the original analysis due to time constraints, damage, or unsuitable preparations. It was apparent that the technicians in Laboratory D missed fibers and misidentified asbestos fibers as non-asbestos.

Re-analysis of human tissue

Laboratory D also performed fiber burden analysis on human tissue with differing results than the study of the authors. Similar to the re-evaluation of bulk analyses, two author–reviewers analyzed the human tissue sample preparations of Laboratory D together and found significant differences in their analyses compared to the technicians who originally analyzed the grids and stubs. We determined that the technicians misidentified anthophyllite asbestos fibers that had been coated with iron and protein (anthophyllite asbestos bodies) as either cleavage fragments or as amosite fibers (Fig. 12). Furthermore, it is the authors' consensus that there are no generally accepted criteria to classify individual fibers as cleavage fragments by TEM when the sample contains attributes of an asbestos fiber or countable structure. When Laboratory D technicians initially looked for asbestos bodies to determine the fiber core, they concluded that most were amosite.

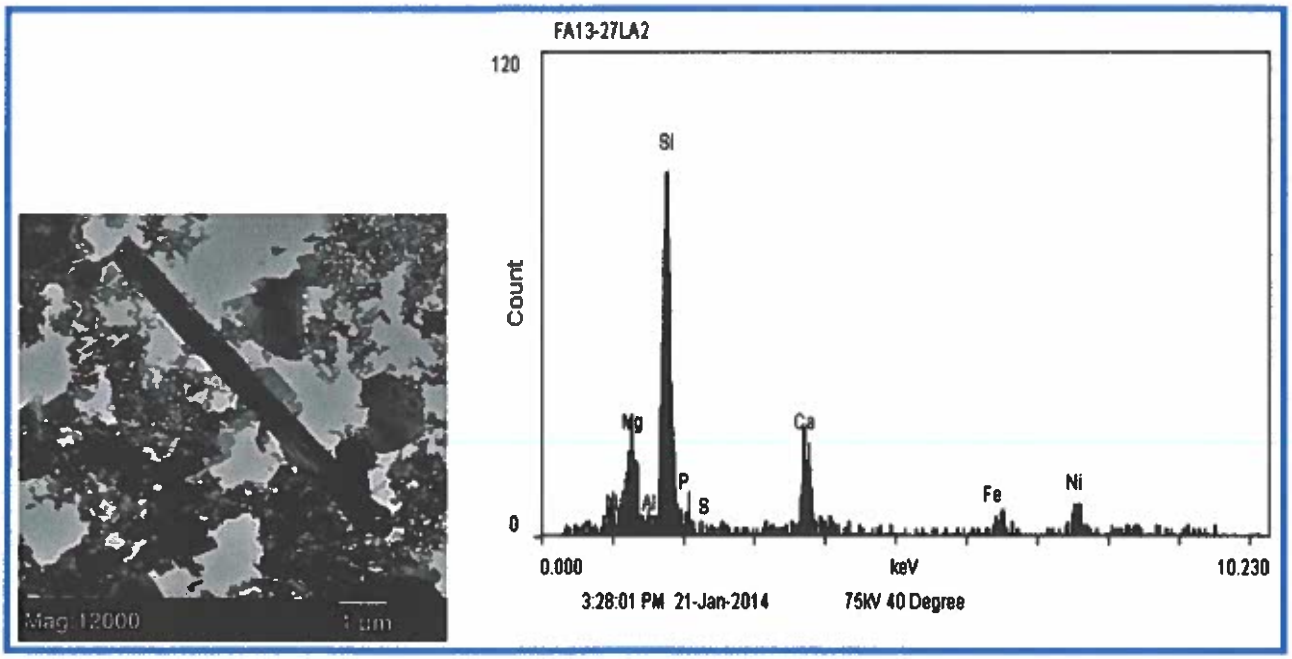


Figure 10 This asbestos fiber is a representative sample removed from the lung tissue of the patient exposed to cosmetic talcum powder. Tremolite asbestos fiber with its corresponding EDS spectra.

the same structures, it was clear that the cores were either anthophyllite or could not be determined because there was exposed fiber core. In previous studies of human tissue having anthophyllite and anthophyllite bodies (Fig. 11), it was common to find that the entire anthophyllite core, even if quite long, was completely coated.

Zone axis confirmation in bulk, tissue, and air

Laboratories A, B, and C confirmed original amphibole asbestos structures by zone axis diffraction. Laboratories A, B, C, and D re-analyzed archived preparations with the intent of confirming amphiboles by zone axis diffraction. In all four sets of re-analyzed preparations, anthophyllite and tremolite asbestos were consistently

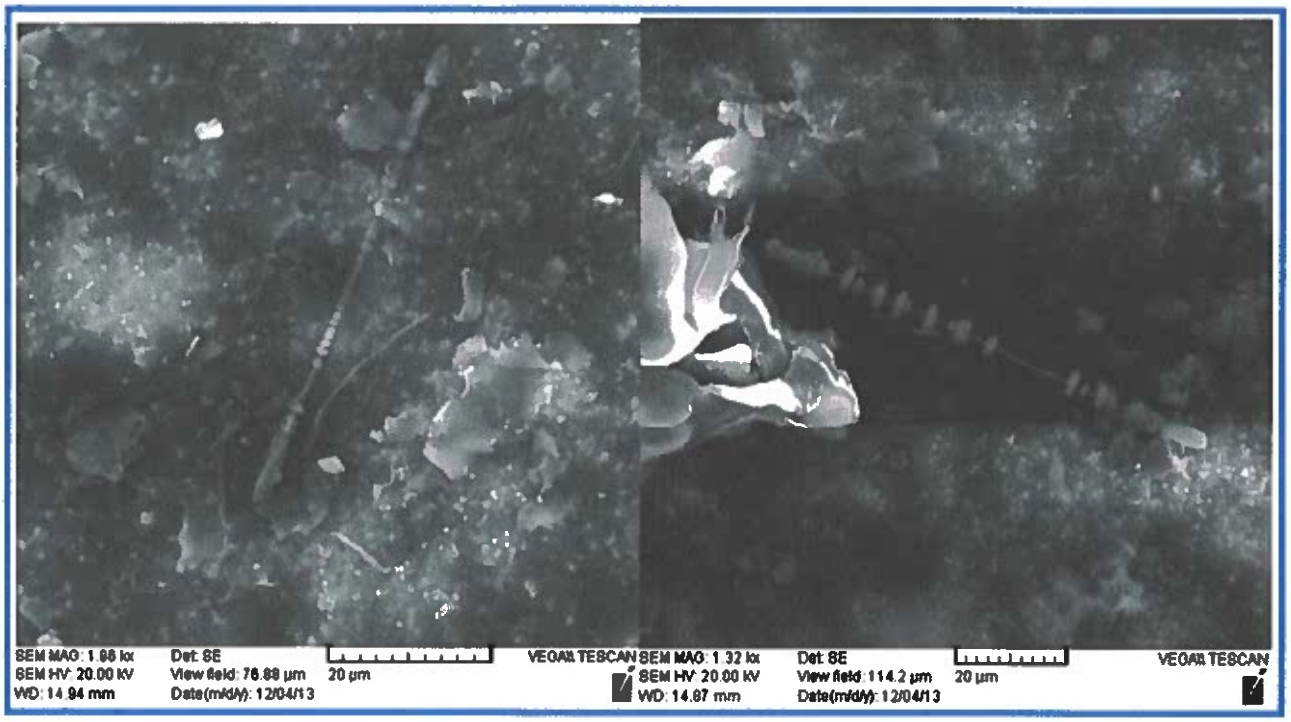


Figure 11 These are asbestos bodies from the patients lung tissue taken by SEM. It is possible to see in the one to the left that the fiber is almost completely covered by the iron protein coating. This is compared to the one at the right which appears to have much more fiber exposed. However, upon EDS testing, it was determined that in both cases, these were anthophyllite

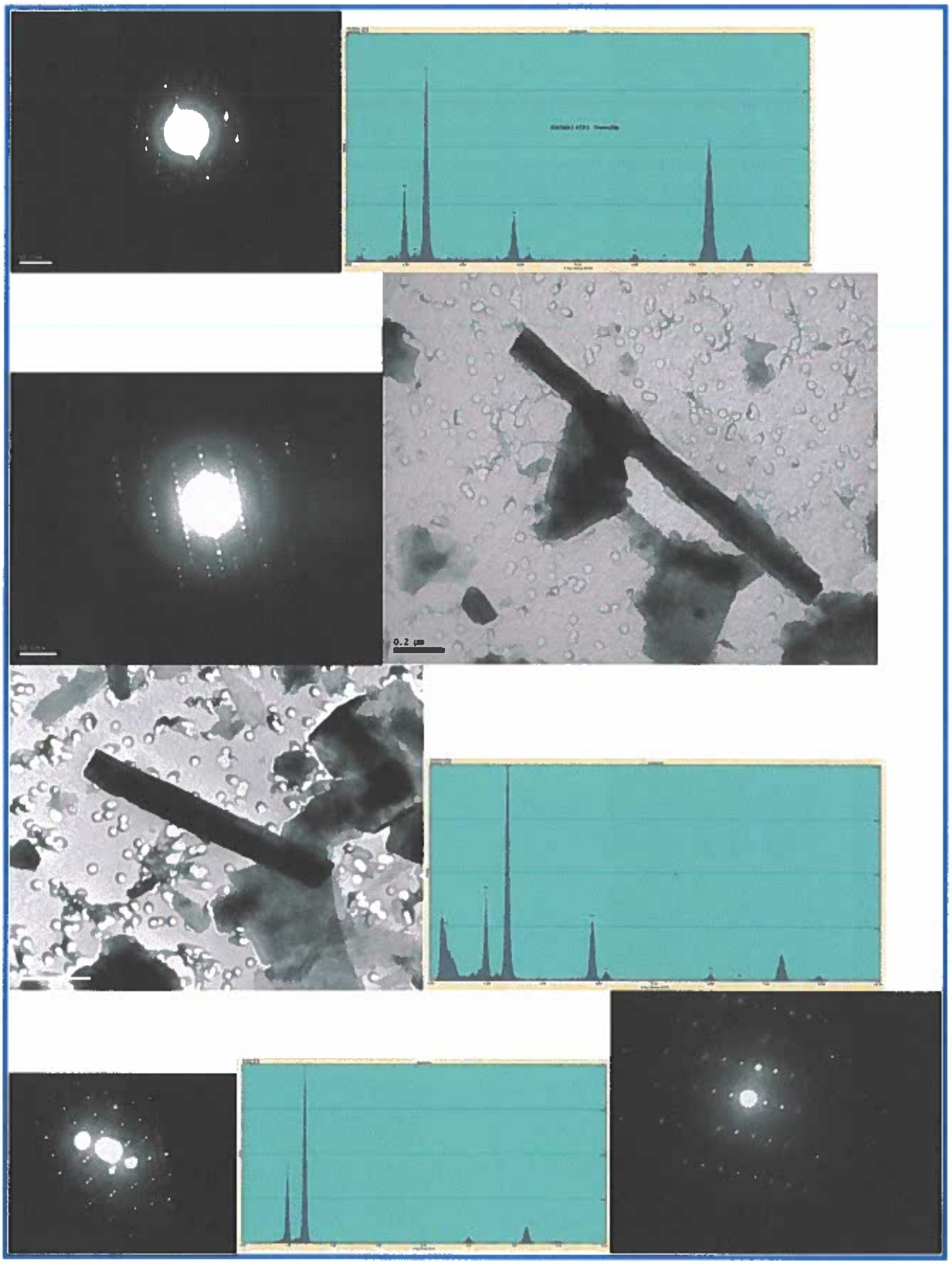


Figure 12 Tremolite and anthophyllite asbestos from re-analyses of 'Lab D' preparations (images, EDS, and SAED).

confirmed by zone axis diffraction pattern measurements. This included confirmation of asbestiform amphiboles, including anthophyllite and tremolite asbestos from the original product testing, from the releasability air tests, and from TEM preparations of lung and lymph node tissues.

Discussion

Historically, many mesotheliomas, particularly abdominal mesotheliomas in women, have been labeled idiopathic due to a lack of an identifiable source for asbestos exposure. Further, there has been an increase in the number of idiopathic pleural and abdominal mesotheliomas in women using this specific brand of talcum powder. There have been a few studies that have examined talcum powder and its potential to cause ovarian tumors.[3–5] The studies were inconclusive, but suggested that talc, asbestos, or both may cause these cancers through vaginal exposure.[4] These studies attributed asbestos found within the women's lesions to result from contact with their partners. There was no consideration for the potential of the asbestos being a contaminant in the women's talcum powder.[3,4] However, it has been reported that cosmetic talcum was contaminated with asbestos, and that asbestos was found in the mines from which the talc originated.[6,9] Our findings indicate that historic talcum powder exposure is a causative factor in the development of mesotheliomas and possibly lung cancers in women.

Talc has been identified as a causative for mesotheliomas in New York talc miners.[31] In recent years, more than 10 women developed mesothelioma and their only source of asbestos exposure was the use of one brand of talcum powder. This study demonstrates that the brand of talcum powder tested contained asbestos. Furthermore, we have traced the asbestos in the talc to the mines from which it originated, into the milled grades, into the product, and finally into the lung and lymph nodes of the users of those products, including one woman who developed mesothelioma.

Based on the testing and re-testing conducted by the authors, it is evident that this product line has been consistently contaminated with asbestos tainted talc derivatives. The amount of asbestos was variable based on the time of manufacture and the talc source. There have been numerous publications that have indicated that the talc in many talc deposits had asbestos contamination.[32–35] The most common types of asbestos were tremolite and anthophyllite. These are the same asbestos fiber types found in the autopsied lungs and lymph nodes tested here for asbestos presence. In a few containers tested in this study, chrysotile was also found, consistent with the source ore geology.

Most, if not all, testing of cosmetic talc was performed using techniques designed for light microscopy, PLM, or by TEM criteria designed to test air and water samples. Testing determined if asbestos levels were above the EPA standards under AHERA or the Occupational Safety and Health Agency standards. in the Yamate method.[23] There are significant limitations to these methods. PLM analysis misses small fine asbestos fibers or fibrils because the limits of the resolution are approximately 0.2–0.5 μm for different forms of light microscopy. Based on our findings, approximately 90% of the fibers identified fall into this category. Determining the number of TEM grid openings to be counted during the analysis requires stopping factors, or limits on the quantity of analysis to be performed. The Draft Yamate method (1984) gives the guidelines of "100 fibers or 10 grid openings, whichever is first."[23] This counting rule was instituted for cost limitation purposes. The Draft Yamate method describes that while this guideline of using 10 full-grid openings represents a judicious compromise between a reasonable experimental effort and a fairly low value of the detection limit, the analysis of additional TEM grid openings reduces the detection limit and improves the precision of the estimates. In the talc study described here, a very low level of detection was desired and therefore, in some cases, as many as 500 plus grid openings were analyzed to reduce the detection limit and improve sensitivity of the test. TEM testing has been adequate for evaluating building material asbestos abatement projects, local air sampling, and potential water contamination with asbestos.[23] However, these criteria are not acceptable for assessing asbestos fiber burden analyses in human tissues and for low asbestos content products that are used intermittently in small quantities over long periods of time, such as cosmetic talcum powder.[36] Talc related asbestos exposures can be heavy at times, above 4000 F/cc. The inhaled asbestos fibers are extremely variable in the causation of asbestos related tumors and fiber burdens found in the deceased woman were within the reported ranges for amphiboles to be causative factors in the development of such a tumor.[37]

Therefore, it is imperative to analyze products such as talcum powder for small amounts of asbestos fibers. This requires that the limits of detection be lower than levels required in a typical Yamate analysis. The author–reviewers observed that the Laboratory D analyses were done using Yamate methodology and no more than 10–25 grid openings on bulk TEM grid preparations were observed.[24] Based on Laboratory D's protocols for testing, millions of fibers/gram of talc would have to present in order to find fibers. Lower concentrations in the ranges found by Laboratories A, B, and C demonstrated that fibers were detectable and present at levels sufficient to cause mesotheliomas.

Although long narrow asbestos fibers are highly carcinogenic, shorter, narrow fibers are also dangerous.[36–38] It is now more common to find shorter narrow fibers in human tissue digestions than

study provides evidence that low concentrations of asbestos in raw materials do not necessarily correlate to low health risk.[38,39] Examples of recent studies of low asbestos content producing significant airborne concentrations in simulated activity include activity-based monitoring of asbestos as it naturally occurs in several sites, as conducted by the EPA and Agency for Toxic Substances and Disease Registry, and vermiculite-containing attic insulation studies.[40] These studies have repeatedly shown that substantial airborne concentrations could be derived from materials with only a fraction of a percent asbestos content.[36] This has been especially true when a product was in a friable state, or where the obvious use of material intimates aerosolization of fibers. Significant airborne concentration can be easily generated from such conditions when asbestos is a constituent.[40–43]

The talc application studies were simulations of exposures to talc used by a deceased woman who had mesothelioma. The air volume in the testing space was 158 cubic feet. This is in the range of the chamber sizes used by talcum powder manufacturers in the 1970s in their studies of the quantity of talcum powder used in normal application. The space used by Russell was 171 cubic feet and the space used by Aylott was between 152 and 163 cubic feet. The amount of material used in the shaker test was 0.37 g. The amount used for the puff applicator test was 6.25 g.[44,45] The shaker test was a light application and the puff a heavy application. However, the heavy application was within the ranges published by Russell of 8.84 ± 8.32 g and Aylott of 2.5 ± 12.5 g. The "talcing times," or the duration of talcum powder application, were approximately 55 seconds for the shaker test and approximately 57 seconds for the puff applicator test.[44,45] These were within the ranges published by Russell of 83 ± 33 seconds and Aylott of 28–78 seconds for adult dusting.[44,45] Laboratories A and B determined that the contaminated talcum powder released inhalable asbestos into the air.

Another issue in this study was the documentation and identification of cleavage fragments. The scientific community has not generally adopted cleavage fragment differentiation criteria.[46] It is unclear how to identify a cleavage fragment once the stone or material has been finely ground. Two criteria for distinguishing cleavage fragments from asbestos fibers have been proposed. The first is that the ends of cleavage fragments have oblique angles and second is that the aspect ratios are all less than 20 : 1. The ends criterion has not been validated with known asbestos/cleavage fragment standards and while an aspect ratio of 20 : 1 suggests that a fiber is likely to be 20 : 1 are also asbestos. As the fiber aspect ratio increases, the percentage of asbestos fibers versus cleavage fragments also increases.[47] However, this criteria falls short when the fiber is extremely thin and is the smallest unit of diameter of a fiber. When these small fibers are removed and analyzed from human tissue, these criteria have to be discarded because enzymes with basic and acidic molecules within cells can leach elements from the surface, causing a breakdown of the fibers, especially when thin in diameter. van Orden *et al.* propose criteria to identify cleavage fragments by SEM.[46] The criteria are based on surface contours which identify a cleavage fragment.[46] However, this method has not been verified and is not generally accepted. There were no photographs of TEM or high-resolution high-magnification SEM provided by Laboratory D, which classified potential asbestos fibers as cleavage fragments

In conclusion, we found that a specific brand of talcum powder contained identifiable asbestos fibers with the potential to be released into the air and inhaled during normal personal talcum powder application. We also found that asbestos fibers consistent with those found in the same cosmetic talc product were present in the lungs and lymph node tissues of a woman who used this brand of talc powder and developed and died from mesothelioma.

Disclaimer Statements

Contributors All authors did studies relevant to the manuscript and all contributed and accepted all the writing.

Funding The work done was paid for by attorneys for litigation purposes. No funds were for writing of this manuscript.

Conflicts of interest Funding for all Labs was provided as part of litigation. No funds were for writing this article. Laboratories are available for defense or plaintiff litigation.

Ethics approval Ethical consent was not needed.

References

1 Robinson BM. Malignant pleural mesothelioma: an epidemiological perspective. Ann Cardiothorac Surg. 2012;1:491–6.
2 Ilgren EB, Wagner JC. Background incidence of mesothelioma: animal and human evidence. Regul Toxicol Pharmacol. 1991;13:133–49.
3 Heller DS, Gordon RE, Katz N. Correlation of asbestos fiber burdens in fallopian tubes and ovarian tissue. Am J Obstet Gynecol. 1999;181:346–7.
4 Heller DS, Gordon RE, Westhoff C, Gerber S. Asbestos exposure and ovarian fiber burden. Am J Ind Med. 1996;29:435–9.
5 Heller DS, Westohoff C, Gordon RE, Katz N. The relationship between peritoneal cosmetic talc usage and ovarian talc

6 Rohl A, Langer A. Consumer talcum's and powders: mineral and chemical characteristics. J Toxicol Environ Health. 1976;2:255–84.
7 Kleinfeld M, Messite J, Langer AM. A study of workers exposed to asbestiform minerals in commercial talc manufacture. Environ Res. 1973;6:132–43.
8 Porro FW, Patten JR, Hobbs AA. Pneumoconiosis in the talc industry. Am J Roentgen. 1942;42:507–24.
9 Paoletti L, Caiazza S, Donelli G, Pocchiari F. Evaluation by electron microscopy techniques of asbestos contamination in industrial, cosmetic and pharmaceutical talcs. Regul Toxicol Pharmacol. 1984;4:222–35.
10 Luckewicz W. Differential thermal analysis of chrysotile asbestos in pure talc and talc containing other minerals. J Soc Cosmet Chem 1974;26:431–7.
11 Weeks RL. Willow Creek Mine Evaluation, 1984; Berg RB. Talc and chlorite deposits in Montana. Montana Bur Mines Geol Mem. 1979;(45).
12 van Gosen B, Lowers HA, Sutley SJ, Gent CA. Using the geologic setting of talc deposits as an indicator of amphibole asbestos content. Environ Geol. 2004;45:920–30.
13 Hopkins OB. A report on the asbestos, talc, and soapstone deposits of Georgia. Geol Surv Georg Bull. 1948;(29).
14 van Horn EC. Talc deposits of the Murphy marble belt. North Carolina Department of Conserv Dev Bull. 1948;(56).
15 Pratt JH. Mining industry in North Carolina. USGS Contributions to Economic Geology annual report. Reston, VA: USGS; 1902.
16 McCrone LC. Analysis of talc by X-ray diffraction and polarized light microscopy, under contract to NIOSH. Atlanta, GA: NIOSH; 1977.
17 Pooley FD. Report of Investigation of Italian mine samples and related powders. Cardiff: University of Cardiff Department of Mineral Exploration; 1972.
18 Grieger GR. Cover letter explanation of analytical results, item MA2270. Westmont, IL: McCrone Associates; 1971.
19 ES Laboratories analytical report WCD 6/72-1. Doral, FL: ES Laboratories; 1972.
20 Department of Chemistry report of analytical results. New York: New York University; 1972.
21 McCrone Associates. Report of analytical results, item MA5500, Talc 1615. Westmont, IL: McCrone Associates; 1977.
22 AHERA. Appendix A to Subpart E — Interim transmission electron microscopy analytical methods, U.S. EPA, 40 CFR Part 763. Asbestos-containing materials in schools, final rule and notice. Fed Reg. 1987;52(210):41857–94.
23 US Environmental Protection Agency. 'Test Method EPA/600/R-93/116 — Method for the determination of asbestos in bulk building materials. Washington, DC: US Environmental Protection Agency; 1993.
24 American Society for Testing and Materials. Standard test method for airborne asbestos concentration in ambient and indoor atmospheres as determined by transmission electron microscopy direct transfer. ASTM D6281-09. West Conshohocken, PA: ASTM; 2009.
25 American Society for Testing and Materials. Standard test method for microvacuum sampling and indirect analysis of dust by transmission electron microscopy for asbestos structure number surface loading. ASTM D5756. West Conshohocken, PA: ASTM; 2003.
26 American Society for Testing and Materials Standard test method for microvacuum sampling and indirect analysis of dust by transmission electron microscopy for asbestos mass surface loading. ASTM D5756. West Conshohocken, PA: ASTM; 2003.
27 American Society for Testing and Materials. Standard test method for wipe sampling of surfaces, indirect preparation, and analysis for asbestos structure number concentration by transmission electron microscopy. ASTM D6480-99. West Conshohocken, PA: ASTM; 1999.
28 National Institute of Occupational Safety and Health. Asbestos and other fibers by phase contrast microscopy (PCM). Method 7400, NIOSH Manual of Analytical Methods. 4th ed. Atlanta, GA: NIOSH; 1994.
29 National Institute of Occupational Safety and Health. Asbestos fibers by transmission electron microscopy (TEM). Method 7402, NIOSH Manual of Analytical Methods. 4th ed. Atlanta, GA: NIOSH; 1994.
30 Wu M, Gordon RE, Herbert R, Padilla M, Moline J, Mendelson D, *et al.* Case Report: Lung disease in World Trade Center responders exposed to dust and smoke: Carbon nanotubes found in the lungs of World Trade Center patients and dust samples. Envron Health Perspect. 2010;118:499–504.
31 Hull MJ. Abraham JL. Case BW. Mesotheliomas among workers in asbestiform fiberbearing talc mines in New York State. Ann Occup Hyg. 2002;46:132–5.
32 Bateman AM. The formation of mineral deposits. New York: John Wiley & Sons, Inc.; 1951.
33 Lamey CA. Metallic and Industrial mineral deposits. New York: McGraw-Hill Book Co.; 1966.
34 Loomis FB. Field book of common rocks and minerals. New York: G.P. Putnam's Sons; 1948.
35 Nititakis JM, McEwen GN, Jr, editors. CTFA compendium method J 4-1. Asbestiform amphiboles minerals in cosmetic talc. In: Cosmetic ingredients test methods. Washington, DC: Cosmetic, Toiletry and Fragrance Association; 1990.
36 Ewing WM, Hays SM, Hatfield R, Longo WE, Millette JA, Zonolite attic insulation exposure studies. Int J Occup Environ Health. 2010;16:279–90.
37 Davis JM, Addison J, Bolton RE, Donaldson K, Jones AD, Smith T. The pathogenicity of long versus short fibre samples of amosite administered to rats by inhalation and intraperitoneal injection. Brit J Exp Pathol. 1986;67:415–30.
38 Suzuki Y, Yuen SR, Ashley R. Short, thin asbestos fibers contribute to the development of human malignant mesothelioma: pathologic evidence. Int J Hyg Environ Health. 2005;208:201–10.
39 Dodson RF, Atkinson MA, Levin JL. Asbestos fiber length as related to potential pathogenicity: a critical review. Am J Ind Med. 2003;44:291–7.
40 EPA. Toxicological review of Libby amphibole asbestos. Washington, DC: EPA; 2001.
41 EPA. Memorandum to superfund national policy managers, EPA regions 1–10. Washington, DC: EPA; 2004.
42 Ewing WM, Hays SM, Hatfield R, Longo WE, Millette JR. Zonolite attic insulation exposure studies. Int J Occup Environ Health. 2010;16:279–90.
43 Hart JF, Spear TM, Ward TJ, Baldwin CE, Salo MN, Elashheb MI. An evaluation of potential occupational exposure to asbestiform amphiboles near a former vermiculite mine. J Environ Public Health. 2009;2009:189509.
44 Russell RS, Merz RD, Sherman WT, Sivertson JN. The determination of respirable particles in talcum powder. Food Cosmet Toxicol. 1979;17:117–9, 121–2.
45 Aylott RI, Byrne GA, Middleton JD, Roberts ME. Normal use levels of respirable cosmetic talc: preliminary study. Int J Cosmet Sci. 1979;1(3):177–86.
46 van Orden DR, Allison KA, Lee RJ. Differentiationg amphibole asbestos from non-asbestos in a complex mineral environment. Indoor Built Environ. 2008;17:58–68.
47 Ilgren EB. The biology of cleavage fragments: a brief synthesis and analysis of current knowledge. Indoor Built Environ. 2004;13:343–56.

EXHIBIT "4"

DECLARATION OF
UNDER PENALTY OF PERJURY

1. "My name is _____. I am competent to make this declaration. The facts stated in this declaration are within my personal knowledge.

2. I am the Custodian of Records of Northwell Health, Inc. I am responsible for ensuring that Northwell Health, Inc. maintains accurate and complete records of its regularly conducted activities.

3. Attached to this declaration are _____ pages of records from Northwell Health Inc..

4. These _____ pages were made at or near the time of the act or event by, or from information transmitted by, someone with knowledge of the facts; were kept by Northwell Health Inc. in the course of regularly conducted activity; and were made as part of the regular practice of that activity. The attached records are the original records or exact duplicates of the original records.

5. I declare under penalty of perjury that the foregoing statements are true and correct."

EXECUTED on _____, 2022.

_____
Declarant